MOOG MEDICAL DEVICES GROUP

Non-Factory Recertification Training

Technical Service Manual

For use with the

2000, 4000, 6000 and PainSmart Series™ Ambulatory Infusion Systems

Moog Medical Devices Group
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REVISION M

REORDER NUMBER 350-9023

Warning: Repair and/or service of Curlin infusion pumps without prior training by Moog could increase patient hazard.
No third party repair or preventive maintenance should be performed without a specific written service agreement with Moog Medical Devices Group.

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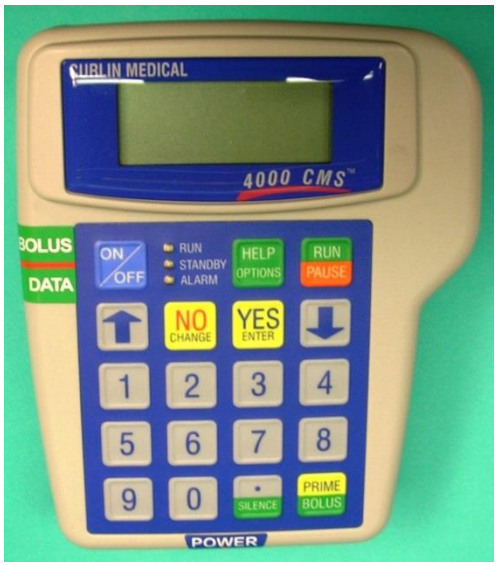
Chapter 1: System Overview

General

The pump consists of the Curvilinear Peristaltic pumping mechanism, sensors, input/output devices, motor control subsystem, safety circuits and a micro-controller.

6000 CMS™

PainSmart



4000

2000

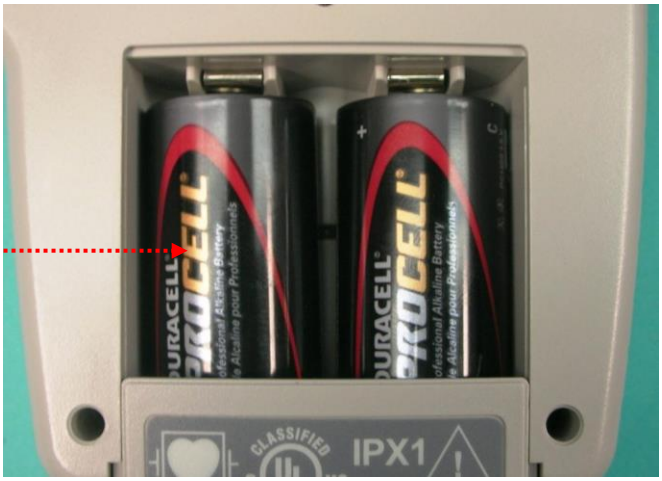
Curlin 2000 Plus™	Curlin 4000 CMS™
General ● 5 Therapy Electronic Ambulatory Pump ● Therapies include: Continuous, PCA, TPN, Intermittent and Variable ● Flow Rates of 0.1 ml to 400ml per hour ● Volume Limits of 1.0 ml to 9,999 ml	**General** ● 7 Mode Electronic Ambulatory Pump ● Therapies include: Continuous, PCA, PCEA,Subcutaneous, TPN, Intermittent & Variable ● Flow Rates of 0.1 ml to 400ml per hour ● Volume Limits of 1.0 ml to 9,999 ml
Performance ● 2 microlitres flow resolution (25 TIMES the resolution of flow of nearest competitor) ● Draws from bags, syringes and bottles	**Performance** ● 2 microlitres flow resolution (25 TIMES the resolution of flow of nearest competitor) ● Draws from bags, syringes and bottles ● Displays Line Pressure readings
Safety ● Set-based, active anti-free-flow design ● Continuous fluid delivery at low rates ● Fluid resistant ● Safe default parameters ● Integrated upstream sensor ● Integrated air-in-line sensor ● Integrated bag pressure sensor ● Alarms include Infusion Complete, Door Open, Set Not Installed, Unattended Pump, Replace Set and Empty Battery ● Mandatory verification of prescription on repeat of Rx ● Incremental Titration control in PCA ● Backlights ON with A/C power. ● Five (*****) digits Access Code.	**Safety** ● Set-based, active anti-free-flow design ● Continuous fluid delivery at low rates ● Fluid resistant ● Safe default parameters ● Integrated upstream sensor ● Integrated air-in-line sensor ● Integrated bag pressure sensor ● Alarms include Infusion Complete, Door Open, Set Not Installed, Unattended Pump, Replace Set and Empty Battery ● Mandatory verification of prescription on repeat of Rx ● Incremental Titration control in PCA ● Backlights ON with A/C power. ● Nine (****-*****) digits Access Code.
Savings ● Uses 2 “C” cell batteries	**Savings** ● Uses 2 “C” cell batteries **Clinical Management System** ● Reduces potential for medication error ● Maximizes scarce nursing time ● Minimizes training/inservice time ● Electronically uploads programs to, and downloads data from the **4000 CMS** pump via a **PDA** and/or **PC** ● Stores “Libraries” of often used Rx protocols and prescriptions ● Provides on-the-run documentation (electronic and hard copy) of Event & Compliance History and Audit-Trail ● Provides “Cautions Page” for instructions ● “Peace-of-mind” feature

Curlin 6000 CMS™	Curlin PainSmart™
General ● Multi-Therapy Pump ● include: Continuous, PCA,Intermittent, TPN, Variable PCEA & Subcutaneous ● Flow Rates of 0.1 ml to 400ml per hour ● Volume Limits of 1.0 ml to 9,999 ml	**General** ● PCA Electronic Ambulatory Pump ● Pain Management therapies include: PCA,PCEA & Subcutaneous ● Flow Rates of 0.1 ml to 400ml per hour ● Volume Limits of 1.0 ml to 9,999 ml
Performance ● 2 microlitres flow resolution (25 TIMES the resolution of flow of nearest competitor) ● Draws from bags, syringes and bottles ● Displays Line Pressure readings	**Performance** ● 2 microlitres flow resolution (25 TIMES the resolution of flow of nearest competitor) ● Draws from bags, syringes and bottles ● Displays Line Pressure readings
Safety ● Set-based, active anti-free-flow design ● Continuous fluid delivery at low rates ● Fluid resistant ● Safe default parameters ● Integrated upstream sensor ● Integrated air-in-line sensor ● Integrated bag pressure sensor ● Alarms include Infusion Complete, Door Open, Set Not Installed, Unattended Pump, Replace Set and Empty Battery ● Mandatory verification of prescription on repeat of Rx ● Incremental Titration control in PCA ● Backlights ON with A/C power. ● Choice of Nine or Five digits Access Code. ● User Configurable Mode, Units and Route ● medLIMITS to enforce user defined limits on major infusion parameters	**Safety** ● Set-based, active anti-free-flow design ● Continuous fluid delivery at low rates ● Fluid resistant ● Safe default parameters ● Integrated upstream sensor ● Integrated air-in-line sensor ● Integrated bag pressure sensor ● Alarms include Infusion Complete, Door Open, Set Not Installed, Unattended Pump, Replace Set and Empty Battery ● Mandatory verification of prescription on repeat of Rx ● Incremental Titration control in PCA ● Backlights ON with A/C power. ● Choice of Nine or Five digits Access Code. ● User Configurable Mode, Units and Route ● medLIMITS to enforce user defined limits on major infusion parameters
Battery Requirements ● Uses 2 “C” cell batteries	**Battery Requirements** ● Uses 2 “C” cell batteries
Clinical Management System – Protocol Library Safety Software ● Electronically uploads programs to, and downloads data from the pump using a PC ● Programmable “Libraries” of often used Rx protocols and prescriptions ● Provides documentation (electronic and hard copy) of Event &Compliance History and Audit-Trail ● Provides “Cautions Page” for instructions ● Can be upgraded in the field.	**Clinical Management System – Protocol Library Safety Software** ● Electronically uploads programs to, and downloads data from the pump using a PC ● Programmable “Libraries” of often used Rx protocols and prescriptions ● Provides documentation (electronic and hard copy) of Event &Compliance History and Audit-Trail ● Provides “Cautions Page” for instructions ● Can be upgraded in the field.

Overview of Curlin Pumps

Electronic Sub-Systems

1 POWER SUPPLIES: The power source for the pump is either the replaceable, internal C-cell batteries or an external power source such as the AC power adaptor.



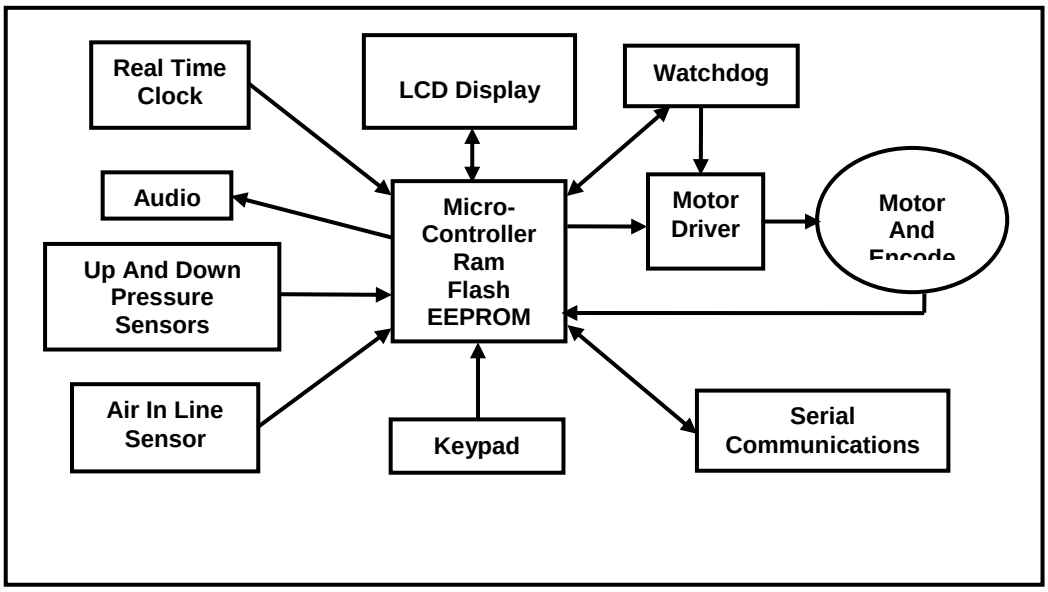


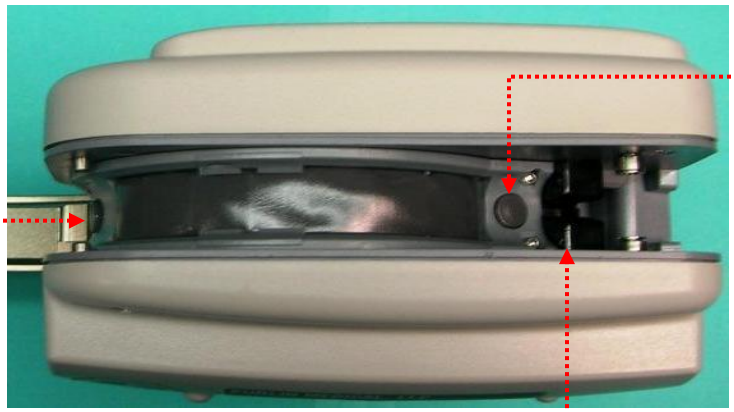
Figure 1.1 Curlin Pump Block Diagram

From the power source, two voltages are generated, 8.3 volts for driving the motor and 5 volts for the logic/analog circuits. Voltage levels are monitored by the micro-controller to ensure they are within specifications for safe pump operation. If at any time the voltages do not meet specification a malfunction will occur, pumping will stop, and the pump will notify the user by displaying an Error Code on the LCD screen.

2 COMPUTER SYSTEM: The computer system includes a 16 bit micro-controller, 256 kilobytes of RAM memory, 512 kilobytes of Flash memory, and 1 kilobyte of EEPROM memory. In addition, the micro-controller contains analog-to-digital converters used for monitoring analog subsystems such as up and down stream pressure sensors. The entire program that makes the pump work is stored in the Flash memory. The RAM memory is used for scratch memory and for History Event storage (Patient History File).

Sufficient memory is available for approximately 6,000 events to be saved. Critical parameters, such as calibration constants which are unique to each pump, are stored in the EEPROM memory.

3 UP AND DOWN PRESSURE SENSORS: The pump monitors the up and down stream pressure of the administration set in order to determine occlusions. If the pressure in the downstream, patient, side of the pump rises to a programmed threshold, the infusion will stop and a down occlusion alarm occurs. On the upstream bag side if the pressure drops to a programmed threshold the infusion will stop and an up stream occlusion alarm occurs. The pressure in the downstream, patient, side is also displayed on the LCD and stored in the history file. Each pump undergoes a calibration procedure which determines calibration constants necessary for accurate calculations of up and down stream pressures.



4 AIR IN LINE SENSOR: The Air in Line sensor detects the presence of air in the downstream patient side of the administration set. This safety system will stop an infusion and generate an air in line alarm if an air bolus greater than the programmed limit passes through it. The size of the maximum permissible air bolus is programmable by the clinician. Safety circuits and software continuously check the Air in Line sensor to confirm that it will properly detect air.

5 AUDIO OUTPUTS: When attention is need by the pump, it will sound its audio device. Various frequencies and duration of beeps are used to inform the user of specific situations such as Power on Self-Test diagnostics, various alerts and alarms. The volume intensity of the audio output is programmable by the user.

6 SERIAL SELF COMMUNICATIONS: A RS-232 serial port is provided for serial communications to and from the pump. Features such as dumping the Patient History File and loading the pump with a new upgraded software program are accomplished through the serial port. The serial communications is according to the following specification:

a. baud rate-9600;

b. number of data bits 8;

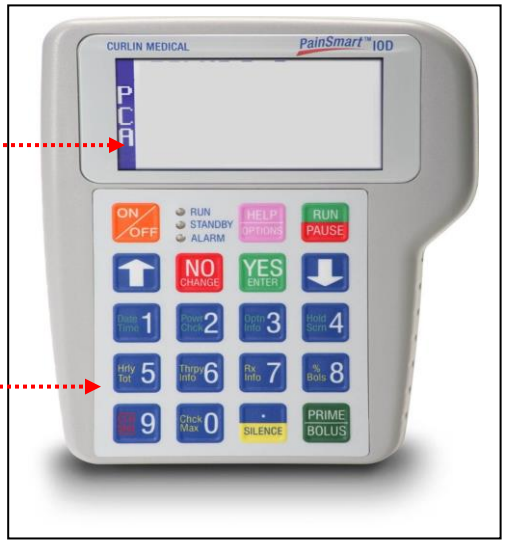
c. number of stop bits-1;

d. parity-none; and;

e. handshake-Xon/Xoff.

The electrical connection to the serial port includes three wires only: Transmit, Receive and Ground.

7 LCD SCREEN: On the LCD is displayed all programming menus, running screens, diagnostics, and instructions when using the pump. The LCD is a graphical LCD consisting of 100 dots horizontally by 32 dots vertically. The intensity of the LCD is programmable by the user and a backlight is provided for enhanced viewing in dim lighting.



8 KEYPAD: The keypad is a sealed membrane type from which the user programs and operates the pump. The keypad is interfaced to the pump PC board via a flexible flat cable. The keys of the keypad have a domed profile and a tactile bounce when they are pressed. The electronic arrangement of keys in a matrix which minimizes the number of interface traces.

9 WATCHDOG SAFETY SYSTEM: At all times, a Watchdog Safety System is actively monitoring proper operation of the pump. To keep the Watchdog satisfied, the micro-controller sends a pulse to it at least every 1.6 seconds. If the micro-controller fails to deliver the pulse then the pump motor drive system is immediately shut down and the micro-controller is notified via non-maskable interrupt. The motor control circuits that power the motor are controlled by the Watchdog circuit so that even if the micro-controller is not functioning, the pump will stop infusion if the Watchdog times out.

10 MOTOR DRIVE: The motor drive circuits uses 8.3 volts from the power supply system and convert it to a proper voltage necessary to cause the motor to run at the correct rate. The micro-controller generates a Pulse Width Modulated (PWM) signal which drives the motor driver circuit. When the duty cycle of the PWM is large, the voltage presented to the motor is high, causing the motor to run at a high rate. When the duty cycle of the PWM is small, the voltage presented to the motor is low, causing the motor to run at a slow rate. The motor drive contains circuits to keep the motor running at constant rates. For example, a feedback loop is provided that senses the current being drawn by the motor which indicates when the motor is about to stall under high load conditions. This current feedback loop will make the voltage presented to the motor to rise, thus causing the motor to generate more power to overcome the high load condition.

In addition safety systems are employed to detect any uncontrolled motor motion. The voltage across the motor is read by the micro-controller to determine if the motor is moving when it was not commanded to do so. Also, the encoder is monitored for any un-commanded movement.

11 MOTOR AND ENCODER: The encoder is an integral part of the motor assembly and the motor shaft is directly coupled to the encoder. The encoder is a hall-effect type and the electronic signal format for channels A and B is Quadrature. When the quadrature encoder channels are decoded in a times 1 (X1) mode, there are approximately 1,728 encoder pulses per each peristaltic of fluid delivery which is approximately 0.085 ml. The single, six pin cable from the motor and encoder assembly contains the motor leads, encoder power and encoder channel A and B.

The motor includes an integral gear-head that reduces shaft rotation by a ratio of approximately 13 to 1. The output of the gear-head drives a worm gear that rotates the peristaltic cam. The peristaltic cam has a cam flag which is monitored by an optical sensor and acts as a secondary encoder in determining pumping activity. This redundant encoder system ensures the micro-controller is aware of any rotation the motor might make.

12 REAL TIME CLOCK: The real time clock provides an accurate time base for keeping track to the current date and time. Besides displaying the current date and time on the Power On Self-Test screen, the date and time are included with each event logged into the patient history file. Other features that also use the real time clock are, delay start and system diagnostics.

Mechanical Sub-Systems

1 THE CURVILINEAR PUMPING MECHANISM: Moog's Curvilinear Peristaltic Pumping Technology was designed to overcome the problems inherent to rotary or linear pumping technologies. This new technology platform has a concave, generally circular and rigid platen for supporting a resilient PVC tube. A multi-lobed cam rotates about the center of the platen, and a plurality of pump fingers ride on the cam as cam followers, and are guided to move in a radial direction toward and away from the platen. Each pump finger consists of a wide face for engaging the tube, and a narrow transverse pinch finger, spring biased to extend beyond the wide face. Further, each pump finger includes rolling balls between the body of the pump finger and the cam to ride on the cam in a manner of roller bearing, reducing wear and power requirement.

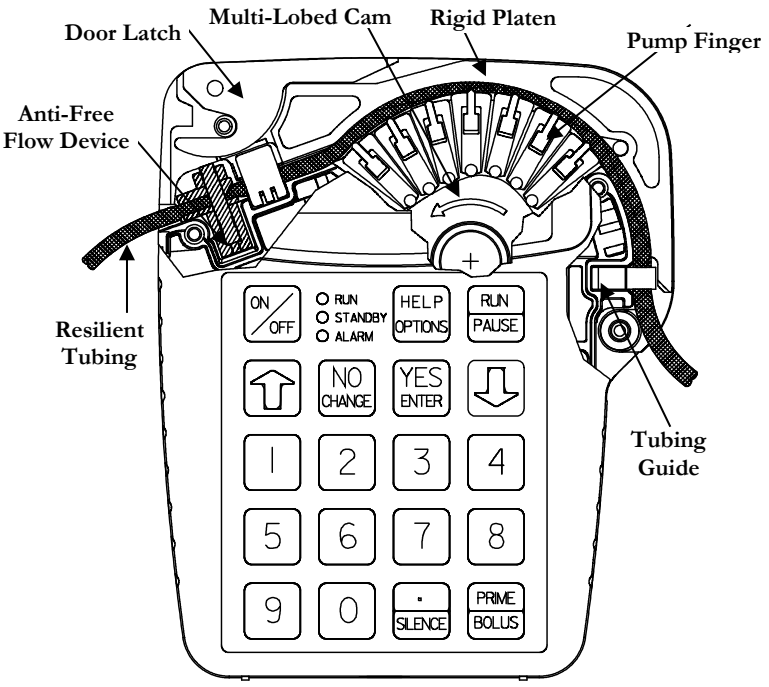


Figure 1.2 Curvilinear Peristaltic Pumping Mechanism

The transverse pinch finger extends from the wide face area of each pump finger. At the tube occluding position, the wide face of the pump finger nearly occludes (does not crush) the tube and the pinch finger completes occlusion without pressing the tube beyond the fully occluded position. This localized occlusions points on the tube preserves the elasticity on the majority of the tube section under the pump fingers, and ensures prolonged tube life and flow accuracy.

When the cam is rotated, the pump finger closest to the highest area on the cam (widest lobe) in the direction of the rotation will be moved outwardly in a radial direction to squeeze the tube against the platen. As the cam continues to rotate, the second pump finger will squeeze the tube as the pinch finger on the first pump finger occludes the tube to force liquid in the tube to flow in the same direction as the cam rotates. As cam rotation continues, the subsequent fingers will sequentially squeeze the tube to push liquid and then occlude the tube. At the same time, the pump finger just behind the lobe will move away from the tube, allowing the tube to expand and fill with liquid. This sequence continues as cam rotation proceeds.

ERROR CODES

Error Code or Alarm	LCD Displayed Message:	History Record Name	Description of Malfunction	Probable Cause	Corrective Action (Where multiple corrective actions are provided, perform them individually and recheck. Soldering requires a minimum of IPC-A-610 skill.)
10	Turn pump OFF/ON or Replace Battery or Call Provider	Motor Control Loss	Motor system is not keeping up with required rate.	▪ Excessive load on the motor. Not sufficient power to drive motor. ▪ Insufficient electric power available to drive motor. ▪ Motor failure.	▪ Confirm connector J28 is connected properly. ▪ Replace PCB, ▪ Replace Mechanism w/ Motor Assembly
11	Turn pump Off/On	Keyboard Buffer Full	Software Malfunction – Pump cannot process key presses fast enough.	Key presses occurring too fast. Pump software running too slow.	Replace PCB.
12	Air Sensor Turn pump Off/ON or Call provider	Air In Line test circuit failure	Safety Monitor software did not successfully test the AIL circuit in timely manner.	Hardware or Software malfunction.	Replace PCB.
13	Pressure Sens DN Check Admin Set turn pump Off/On	Bad Down Strain Beam	Voltage measured from the Down Stream Strain Beam is too low.	▪ Installed administration set is too old or does not meet specification. ▪ R17 needs calibration and/or strain beam constants need recalibration.	▪ Replace set and Resume. ▪ Confirm good solder joint on all leads of R17. ▪ Recalibrate Down Stream strain beam pot R17. Then conduct calibration of Out Strain Beam from factory menu. ▪ Replace PCB.
14	Pressure Sens UP Check Admin Set Turn pump Off/On	Bad Up Strain Beam	Voltage measured from the Up Stream Strain Beam is too low.	▪ Installed administration set is too old or does not meet specification. ▪ R15 needs calibration and/or strain beam constants need recalibration.	▪ Replace set and Resume. ▪ Confirm good solder joint on all leads of R15. ▪ Recalibrate Down Stream strain beam pot R15. Then conduct calibration of Out Strain Beam from factory menu. ▪ Replace PCB.
15	Turn pump Off/On or Call Provider	Bad Encoder	Motor's Encoder is not properly reporting motor motion.	Hardware failure in Encoder or Encoder circuit.	▪ Check solder on J32. ▪ Replace Mechanism w/ Motor Assembly. ▪ Replace PCB.
16	Turn pump Off/On or call Provider	Bad Analog to Digital Conversion	Hardware failure – Analog to Digital conversion circuit has failed to convert in timely manner.	Analog to Digital circuit failure.	Replace PCB.
17	Turn pump OFF Call Provider	Bad Clock	Clocking rates of Real Time Clock and System Oscillator do not match properly.	System Oscillator running at wrong rate or Real Time Clock circuit failure.	Replace PCB.
18	Call Provider	Bad Air In Line comparator register reading from FPGA.	Air In Line Comparator register in FPGA reports wrong value.	Hardware failure in FPGA circuit.	Replace PCB.
19	Turn Pump OFF Call Provider	Bad Door Sensor	Self testing of Door Sensor indicates broken door sensor.	Broken door sensor or door circuit failure.	▪ Check connection of Flex Circuit to PCB J32. ▪ Replace Mechanism w/ Motor Assembly. ▪ Replace PCB.

Error Code or Alarm	LCD Displayed Message:	History Record Name	Description of Malfunction	Probable Cause	Corrective Action (Where multiple corrective actions are provided, perform them individually and recheck. Soldering requires a minimum of IPC-A-610 skill.)
20	Empty Lithium Battery Call Provider	Empty Lithium Battery	Backup Battery for non-volatile RAM and Real Time Clock is too low	Excessive current draw from Lithium Battery.	▪ Replace Lithium battery. Check current draw from Lithium Battery (less than 50 micro-amps.) ▪ Replace PCB.
21	Turn pump Off Call Provider	Bad Tristate Pin	Reading of port for power managed control circuits indicates power management control is stuck on.	Hardware failure in FPGA.	Replace PCB.
22	Turn Pump OFF Call Provider	Bad Test Pin	Reading of port for factory test jumper indicates factory test jumper is installed.	Factory test jump is installed.	▪ Check for and remove if installed - jumper J35. ▪ Replace PCB.
23	Turn Pump OFF Call Provider	Bad Reference Voltage	Voltage reference used by A to D converter is out of specification.	A to D circuit or Voltage Reference circuit failure.	▪ Reload software. ▪ Replace PCB.
24	Turn Pump OFF Call Provider	Bad Motor Supply	Motor supply voltage is too high.	Motor power supply circuit failure.	Replace PCB.
25	Stalled Pump Turn pump OFF/ON or Call Provider	Broken Motor Shaft	CAM encoder counts do not match Motor encoder counts.	CAM flag not rotating or Motor encoder failure.	▪ Replace Mechanism w/ Motor Assembly. ▪ Replace PCB.
26	Turn Pump OFF Call Provider	Bad Motor Inhibit	The motor inhibit circuit failed to inhibit the motor from running when set to inhibit state.	Motor Inhibit circuit failure.	Replace PCB.
27	Turn Pump OFF Call Provider	Bad Motor Supply Enable	The motor power supply enable circuit failed to disable power to the motor when set to disable state.	Motor supply enable circuit failure.	▪ Reload software. ▪ Replace PCB.
28	Turn Pump OFF Call Provider	Bad Motor Logic Enable	The motor logic enable circuit failed to disable the motor when set to disable state.	Motor Logic enable circuit failure.	Replace PCB.
29	Low Alarm Batt Connect AC Adapt Turn pump OFF/ON	Low Auxiliary Battery	The Auxiliary Alarm battery is not charge to a sufficient level.	Alarm may have been running until Auxiliary Alarm battery was fully drained.	▪ Connect pump to AC Battery Eliminator and turn power off/on to pump. May require turning pump off/on a few times. ▪ Check/replace BT2 (NiMH battery.) ▪ Replace PCB.
30	Turn Pump OFF Call Provider	Bad Auxiliary Battery	Voltage of Auxiliary Alarm Battery is greater than maximum specified level.	Auxiliary Alarm Battery charger circuit failure.	▪ Check/replace BT2 (NiMH battery.) ▪ Replace PCB.
31	Turn Pump OFF Call Provider	Audio Main Speaker Low	During Self-Test, Main speaker did not sound to appropriate level.	Main Speaker failure or current path diode failure.	▪ Check speaker connection. ▪ Check/replace D31. ▪ Replace PCB.
32	Turn Pump OFF Call Provider	Audio Main Speaker High	During Self-Test, Main speaker did not sound to appropriate level.	Main Speaker current path diode failure.	Check/replace D31. Replace PCB.

Error Code or Alarm	LCD Displayed Message:	History Record Name	Description of Malfunction	Probable Cause	**Corrective Action** (Where multiple corrective actions are provided, perform them individually and recheck. Soldering requires a minimum of IPC-A-610 skill.)
33	Low Alarm Audio Connect AC Adapt Turn pump OFF/ON	Audio Auxiliary Speaker Low	During Self-Test, Auxiliary speaker did not sound to appropriate level.	Auxiliary Alarm battery not fully charged or Auxiliary Speaker failure or current path diode failure.	▪ Connect pump to AC Adapter for 1 minute and turn power off/on to pump. May require turning pump off/on a few times. ▪ Check/replace D13: forward resistivity should be greater than 1K ohm. ▪ Check/replace BT2 (NiMH battery.) ▪ Replace PCB.
34	Turn Pump OFF Call Provider	Audio Auxiliary Speaker High	During Self-Test, Auxiliary speaker did not sound to appropriate level.	Auxiliary Speaker current path diode failure.	▪ Replace D13. ▪ Replace PCB.
35	History File Turn pump OFF/ON	History Log Erased	Bad data was found in the History Log and then was erased.	Software error.	▪ Initialize EPROM and perform all calibrations. ▪ Replace PCB if reoccurs.
36	Bad Cal Data Turn pump OFF Call Provider	Bad EEPROM Data CRC value	The stored CRC value for the EEPROM calibration data does not match the calculated CRC of the same data.	EEPROM circuit failure.	▪ Initialize EPROM and perform all calibrations. ▪ Replace PCB if reoccurs.
37	Turn Pump OFF Call Provider	Analog to Digital Converter did not Run	The Analog to Digital converter circuit did not run or finish running in a timely manner.	Analog to Digital circuit failure.	Replace PCB if reoccurs.
38	Turn Pump OFF Call Provider	Air In Line Circuit not Tested	During an infusion the Air In Line sensor did not get tested at the prescribed times.	Software error.	Replace PCB.
39	Turn Pump OFF Call Provider	Bad EEPROM Data CRC 2	The stored CRC value for the EEPROM calibration data does not match the calculated CRC of the same data.	EEPROM circuit failure.	▪ Initialize EEPROM and recalibrate volume, in strain beam, and out strain beam. ▪ Replace PCB if reoccurs.
40	Turn Pump OFF Call Provider	Bad EEPROM Data Header	Header Data read from EEPROM doesn't match signature string.	EEPROM circuit failure or software error.	▪ Initialize EEPROM and recalibrate volume, in strain beam, and out strain beam. ▪ Replace PCB if reoccurs.
41	Turn Pump OFF Call Provider	Bad Calibration Data	The stored EEPROM calibration data is out of range.	Pressure was applied on reversed side of set during pressure occlusion calibration.	▪ Recalibrate pressure occlusion alarm, initialize RAM and reset date/time. ▪ Return pump to Moog.
45-46	Turn Pump OFF Call Provider	Bad Encoder	Motor's Encoder is not properly reporting motor motion.	Hardware failure in Encoder or Encoder circuit.	▪ Replace mechanism with motor assembly. ▪ Replace PCB.

Error Code or Alarm	LCD Displayed Message:	History Record Name	Description of Malfunction	Probable Cause	Corrective Action (Where multiple corrective actions are provided, perform them individually and recheck. Soldering requires a minimum of IPC-A-610 skill.)
100-159	Turn pump OFF/ON or Call Provider	Various Software Errors	Software failed to function properly.	Software error.	▪ Reload software, initialize EPROM, RAM and recalibrate pump. ▪ Replace PCB if reoccurs.
160	Stuck PERIOD Key Turn pump OFF/ON or Call Provider	Stuck Period / Silence Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
161	Stuck ON OFF Key Turn pump OFF/ON or Call Provider	Stuck On / Off Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
162	Stuck 0 Key Turn pump OFF/ON or Call Provider	Stuck 0 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
163	Stuck 1 Key Turn pump OFF/ON or Call Provider	Stuck 1 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
164	Stuck 2 Key Turn pump OFF/ON or Call Provider	Stuck 2 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
165	Stuck 3 Key Turn pump OFF/ON or Call Provider	Stuck 3 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
166	Stuck 4 Key Turn pump OFF/ON or Call Provider	Stuck 4 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
167	Stuck 5 Key Turn pump OFF/ON or Call Provider	Stuck 5 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
168	Stuck 6 Key Turn pump OFF/ON or Call Provider	Stuck 6 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
169	Stuck 7 Key Turn pump OFF/ON or Call Provider	Stuck 7 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.

Error Code or Alarm	LCD Displayed Message:	History Record Name	Description of Malfunction	Probable Cause	**Corrective Action** (Where multiple corrective actions are provided, perform them individually and recheck. Soldering requires a minimum of IPC-A-610 skill.)
170	Stuck 8 Key Turn pump OFF/ON or Call Provider	Stuck 8 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
171	Stuck 9 Key Turn pump OFF/ON or Call Provider	Stuck 9 Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
172	Stuck UP Key Turn pump OFF/ON or Call Provider	Stuck Up Arrow Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
173	Stuck NO Key Turn pump OFF/ON or Call Provider	Stuck No / Change Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
174	Stuck YES Key Turn pump OFF/ON or Call Provider	Stuck Yes / Enter Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
175	Stuck DOWN Key Turn pump OFF/ON or Call Provider	Stuck Down Arrow Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
176	Stuck RUN Key Turn pump OFF/ON or Call Provider	Stuck Run / Pause Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
177	Stuck HELP Key Turn pump OFF/ON or Call Provider	Stuck Help / Options Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
178	Stuck PRIME Key Turn pump OFF/ON or Call Provider	Stuck Prime / Bolus Key	Key is Stuck On.	Key is pressed and held on for more than 20 seconds or keypad is broken.	▪ If key was pressed, release it. ▪ Replace front case w/ keypad. ▪ Replace PCB.
179	Bolus Cord Unplug Cord Turn pump OFF/ON	Stuck Remote Bolus Switch	Remote bolus switch is stuck On.	Remote bolus switch is plugged in and broken or bolus switch circuit failure. Short on pins or solder side of lemo connector.	▪ If bolus was pressed, release it. ▪ Replace bolus cord/switch assembly. ▪ Replace PCB.
180	Turn pump OFF/ON or Call Provider	Invalid Key	An invalid key code was read from the Key Pad.	Key pad failure.	▪ Replace front case w/ keypad. ▪ Replace PCB if reoccurs.
200-211	Turn pump OFF/ON or Call Provider	Various Software Errors	Software failed to function properly.	Software error.	Replace PCB if reoccurs.

Error Code or Alarm	LCD Displayed Message:	History Record Name	Description of Malfunction	Probable Cause	**Corrective Action** (Where multiple corrective actions are provided, perform them individually and recheck. Soldering requires a minimum of IPC-A-610 skill.)
212	Turn pump OFF Call Provider	Bad EEPROM Write	Data written to the EEPROM was read back but did not match what was written.	EEPROM circuit failure.	Replace PCB.
300	Turn pump OFF Call Provider	Stack Overflow	Microprocessor overflowed its stack.	Software or hardware failure that generates too many interrupts.	Replace PCB.
301	Turn pump OFF Call Provider	Bad Flash	The CRC signature did not match the calculated CRC during power on self-test.	Corrupted code in flash.	Replace PCB.
302	Turn pump OFF Call Provider	Bad Run Time Flash	The runtime calculated CRC value of critical code did not match its programmed CRC value.	Corrupted code in flash.	Replace PCB.
303	Turn pump OFF Call Provider	Bad Ram	The RAM did not pass its power on self-test.	RAM circuit failure.	Replace PCB.
304-307	Turn pump OFF Call Provider	Various Software Errors	Software failed to function properly.	Software error.	Replace PCB if reoccurs.
308	Watch Dog Call Provider	Bad Watch Dog Test	The Watch Dog circuit did not pass its power on self-test.	Watch Dog circuit failure.	Replace PCB.
309	Turn pump OFF Call Provider	Stopped Motor Motion Count	The motor's encoder registered motor motion when the motor was not supposed to move.	Motor drive circuit failure.	Replace PCB.
310	Turn pump OFF Call Provider	Stopped Motor Motion Volt	Voltage was present on the motor circuit when the motor was not supposed to move.	Motor drive circuit failure.	Replace PCB.
311-312	Turn pump OFF/ON Or Call Provider	Various Software Errors	Software failed to function properly.	Software error.	Replace PCB if reoccurs.
313	Turn pump OFF Call Provider	Negative Motor Motion	Motor was moving the wrong direction.	Motor circuit failure or mechanical hardware failure.	▪ Replace Mechanism w/ Motor Assembly. ▪ Replace PCB.
314-320	Turn Pump OFF Call Provider	Various Software Errors	Software failed to function properly.	Software error.	▪ Replace PCB.
Air In Line ALARM	ALARM AIR IN LINE	ALARM: AIR IN LINE	Reoccurring Air in Line alarm when air is not present in set.	▪ Air bubble trapped inside set near AIL sensor. ▪ Hardware failure at L5 or L6. Flex circuit broken where AIL sensor solders to it.	▪ Bleed air from set. ▪ Check/Replace L5 or L6 if no continuity. ▪ Check/replace flex circuit for break at solder for AIL sensor. ▪ Replace Mechanism w/ Motor Assembly.
Empty Battery ALARM	ALARM Empty Battery (note upper case letters E and B)	ALARM: Empty Battery	Motor supply voltage (nominally 8.3 volts) is too low.	▪ Low C-Cell batteries. ▪ Failure of 8.3 volt power supply.	▪ Replace batteries. ▪ Replace PCB.
empty battery ALARM	ALARM empty battery (note lower case letters)	ALARM: empty battery	Voltage measured at C-cell batteries is too low.	▪ Low C-cell batteries.	▪ Replace batteries.

Hx File Alert Records

Certain alerts will post history records. Alerts are not a severe as alarms; for example, an Alert will not stop an infusion but an Alarm will. These alerts records are as follows:

Alert Record	Description
Alert LOW BAT	Alert Low Battery indicates the pump has alerted the user that the C-cell batteries or the external lead acid battery are low.
Alert MOT SUP	Alert MOT SUP indicates that the motor supply voltage is low. This could be caused by weak or low C-cell batteries.
Alert MAINT DUE	The Alert Maintenance Due indicates that the pump is due for periodic maintenance. No functionality of the pump is reduced, however, this alert will continue to occur each time the pump is turned on until the Maintenance Due date is changed.
Alert AmTBI/BAG OVR	The Alert Amount TBI/BAG Override indicates that the user has chosen to start/resume with the amount to be infused greater than the programmed bag volume. This can occur when the Bag Volume is reduced due to pump priming which deducts volume from the Bag Volume but will leave the Amount TBI unchanged.

Hx File Alarm Records

Alarm records are recorded each time an alarm occurs on the pump. Alarms will stop an infusion if one is in progress. The alarm records are as follows:

Alarm Record	Description
Alarm UNATTENDED	The Unattended Alarm record indicates that the pump was left in a paused state (an infusion had started running and was then pause). This alarm occurs to draw the attention of the user to resume the infusion.
Alarm DOOR OPEN OR SET NOT PROPERLY INSTALLED	The Door Open or Set Not Properly Installed alarm record indicates that the door was opened or the administration set detector failed to detect the set while an infusion was running.
Alarm HIGH UP PRESSURE	The High Up Pressure alarm record indicates that a high pressure was detected in the up stream side of the administration set while the pump was infusing. This is usually due to some excessive pressure being applied to the bag or syringe.
Alarm EMPTY BATTERY	The Empty Battery alarm record indicates that the C-cell batteries or the Lead Acid battery are too low to properly operate the pump. Low Battery Alerts should have provided warning to the user that it was time to change the batteries prior to the Empty Battery Alarm. These alerts would be recorded prior to the Empty Battery alarm.
Alarm COMM TIMEOUT	The Communication Timeout alarm record indicates that during a CMS communications process with the pump the communications stopped for too long and the process was aborted by the pump.
Alarm UPLOAD CHAR ERR	The Upload Char Err Alarm record indicates that during a CMS communications process with the pump the character echoed back from the CMS system to the pump did not match what the pump had sent to the CMS system.
Alarm UPLOAD CkSum ERR	The Upload Check Sum Error alarm record indicates that at the end of a CMS communications process with the pump (i.e., upload of a prescription) the Check Code for the communication process did not match the Check Code the pump had calculated for the same communication process.
Alarm CMS NOT ENABLED	The CMS Not Enabled alarm record indicates that the pump with which a CMS system is trying to communicate with is not CMS enabled.

Chapter 2: The NFR Traveler

The FDA has published a regulation for quality systems that includes a requirement for keeping records of all medical devices manufactured. The document can be found by following the link below:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

The following sections in particular explain the need for maintaining up-to-date records of all service processes performed on medical devices.

Sec 820.75 Process Validation

Sec 820.784 Device History Record

Sec 820.200 Servicing

The NFR Traveler (PN: 390-9041 Rev C) serves as the Documentation (mentioned in the sections above) for these events. The Device Histories are updated using the information contained in the NFR Travelers.

Whenever you need to perform an NFR procedure on a pump, prepare a copy of the NFR Traveler first. Fill out the top portion of the traveler before you begin the NFR procedure. The name on the "Technician" field should **always** be the same person signing the form, and the initials seen on each data field should be of the same person. Otherwise, the information is not valid even if all tests passed. If there are more than one person performing the tests, both names should appear as the Technician, and both should sign the form. In each case, the technicians should have been trained and certified on the NFR procedure.

Do not leave any field blank. Put "N/A" of "Not Applicable" on the fields that do not require data. Make sure that you are only putting correct information on the traveler.

Only a certified technician should sign and initial the NFR Traveler. If you are having somebody uncertified help you record the data as you perform the tests, do not have them initial or sign the form. Do not have them perform the tests, either. If another certified technician is helping you, both need to sign the form, as noted earlier.

A sample of the NFR Traveler is shown on the following page. A copy of it is also provided in the NFR Training Kit.

TRAVELER:SELF RECERTIFICATION AND REPAIR - CURLIN PUMPS Document 350-9041 Rev C

PUMP SERIAL NO.:	**DATE:**
SOFTWARE REV ON PUMP:	**TECHNICIAN:**
Account Number:	**Property of:**
Contact:	**Return to:**
Street Address:	**Phone:**
City, State, ZIP:	**PCB #Old_____ New_____** **Mech #Old New**

Note: If no calibration is required, not applicable in those sections

Description	Data	Initial By	Date	P/F	Comments
Check Pump Configuration					
Display Pump History and Initialize Pump					
Door Sensor and Tubing Guide					
Tubing guide installed: Door Closed					
Latch and Door Opened: Door Open					
Volume Accuracy Test					
VTBI=10ml RATE-125ml/hr: Infused 9.80 to 10.20ml					
Volume Accuracy Calibration					
Prime volume calibration set					
Amt TBI (@ 100ml/hr)	35.0 ml				
Scale					Same as Calculated Value
Ratio					
VTBI=10ml RATE=125ml/hr: Infused 9.80 to 10.20ml					
Check All Safety Systems					
Input Strain Beam after 2 minutes (2,400 - 1,800)					
Output Strain Beam after 2 minute (2,000 - 1,400)					
Keypad					
Door Open					
Air In Line Sensor					
Up Occlusion					
Down Occlusion					
Auxiliary Alarm System					
External Power Input					
Bolus Cable					
Peristaltic CAM Encoder Sensor (Speed Up Cycle)					
40 PSI Back Pressure Test					
Pump Generates >40 psi pressure @ 20ml/hr					
No pressure drop During Pumping @ 20ml/hr					Before 40 psi, pressures drops > 10 psi not allowed
Down and Up Occlusion Test					
Low Down Occlu Alarm: 6.0 to 10.0 PSI					
Pump Re-starts after clearing Down Occlusion					
High Down Occlu Alarm: 16.0 to 20.0 PSI					
Pump Re-starts after clearing Down Occlusion					
Up Occlu Alarm: -4 to -8 PSI (-16.3 to 8.1 inhg)					
Alarm clears after pressing RUN/PAUSE Key					
Pressure Sensors Baseline Calibration					
Instrn: 2.100 at 4 min (+/- 0.050)					
Outstr: 1.700 at 3 min (+/- 0.050)					
Remove Set. Instrn: <= 0.050					
Remove Set. Outstrn: <= 0.050					
Conclusion					
Set New Maintenance Date					
Set Date and Time					
Reconfigure Pump/Display Final Pump History					
Print and attach Recertification Results					

Mail to: Moog Medical Devices Group, Attn: Service Dept. - Self Recertification 4314 Zevex Park Lane, Salt Lake City, UT 84123	Fax to: Moog Medical Devices Group (801) 264-1051 Attn: Service Dept. - Self Recertification

Technicians Signature below certifies, under penalty of perjury, that he/she has followed the manual 350-9023 Rev J

Technician Signature:_____

InfoCard #: 350-9041, Rev #C, Effective Date: 08 Feb 2011
Title:TRAVELER NON-FACTORY SERVICE INFUSION

Fig 2.1 Sample NFR Traveler

Chapter 3: Service Software

Required Equipment

a. Non-Factory Recertification Software, NFR (Moog P/N: 350-7021).
b. Non-Factory Recertification Software Version 2, NFR (Moog P/N: AS-45914)
c. Non-Factory Service Traveler (Moog P/N: 350-9041).
d. Data Interface Cable for PC (Moog P/N: 340-2011).
e. **Keyspan** USB Serial Adapter (P/N: USA-19HS) – Highly recommended
f. Personal Computer with Microsoft Windows: 2000 or XP.

Overview

The NFR Procedure is accomplished by connecting the pump to the NFR Software and following the steps outlined in this manual. There are two versions of the NFR software. The older version (350-7021) is for use on 2000 and 4000 series pumps, and for 6000 series pumps that has software version earlier than v. 2.00. The newer version (AS-45914) is to be used on 6000 series and PainSmart pumps whose software version is v2.0x.

Make sure your pump is compatible with the software version of the NFR software you are using. The older NFR software (referred to here as Rev R5) will not be able to read the v2.0x pump software, and the newer NFR software (referred to here as V2) will not read the older pump software versions.

Install the NFR Software version that you need into your PC. A desktop PC with Windows version Vista, or Win 8 will find that the NFR software might not always work on these PCs. A PC with Win 7 must run the NFR software as an admin as detailed below.

SET-UP

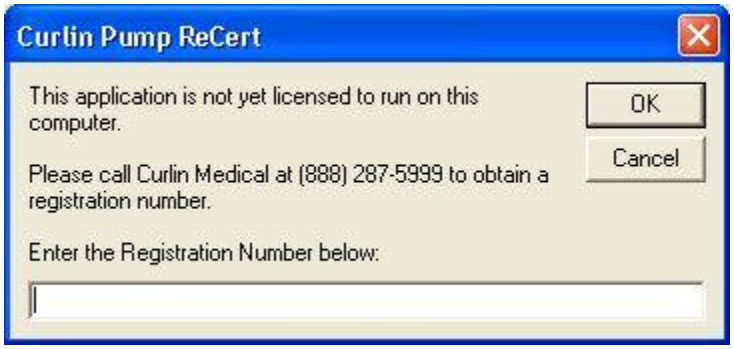
Install the service software into your PC. There are a few differences in installing the 350-7021 and theAS-45914. The instructions immediately below pertain to the older NFR version, referred to here as the Pump Recertification Utility (PRU) Software. After installing the PRU, you will need to configure it before it is ready to use.

Configure PRU

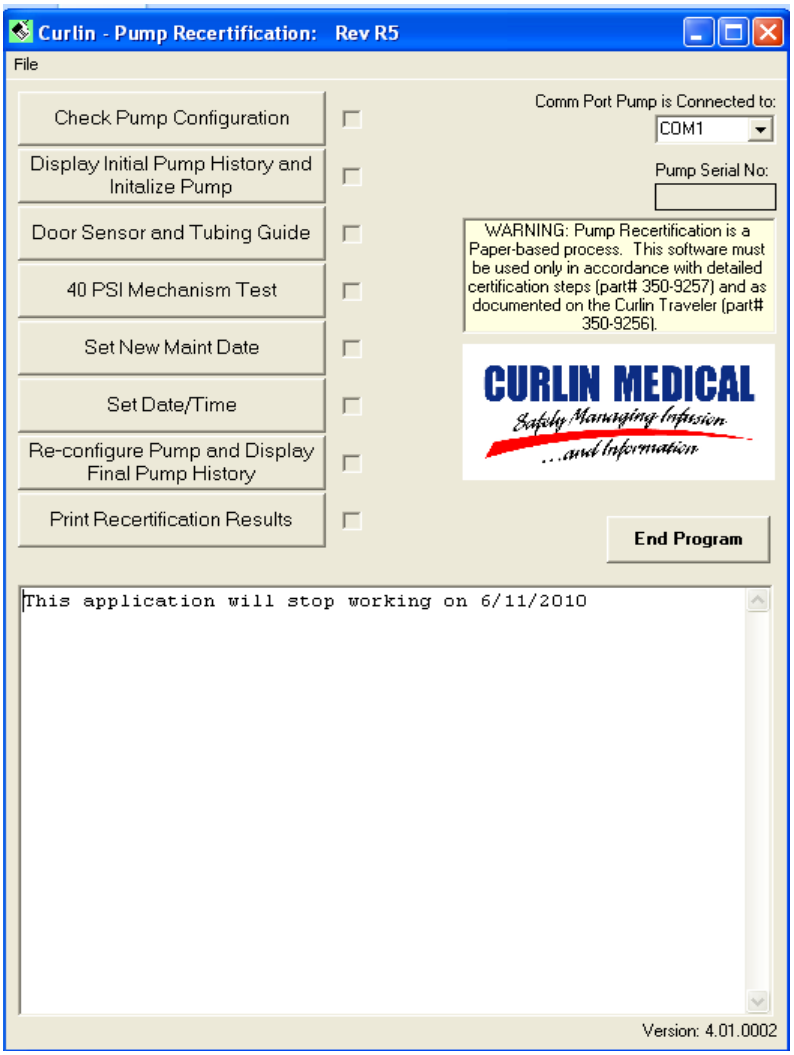
Start the PRU program by double clicking the icon. You will see the image below. Verify the correct date and click OK.

Curlin - Pump ReCertification
Confirm today's date: 10/7/2008
Click 'OK' if correct, or
Click 'Cancel' then set the correct date and time and re-start this application.
OK
Cancel

After you click OK, the image below will appear. Type in the registration code. The registration code can be obtained by calling Moog Customer Advocacy Department. The code changes every day and the software is good to use for 1 year (365 days) after installing. Use the code to register the software as soon as you obtain it.


Curlin Pump ReCert
This application is not yet licensed to run on this computer.
OK
Cancel
Please call Curlin Medical at (888) 287-5999 to obtain a registration number.
Enter the Registration Number below:

After you type in the registration code, the software is ready to use. The image below will be shown. You will not need another registration code until after 365 days.


Curlin - Pump Recertification: Rev R5
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 6/11/2010
Version: 4.01.0002

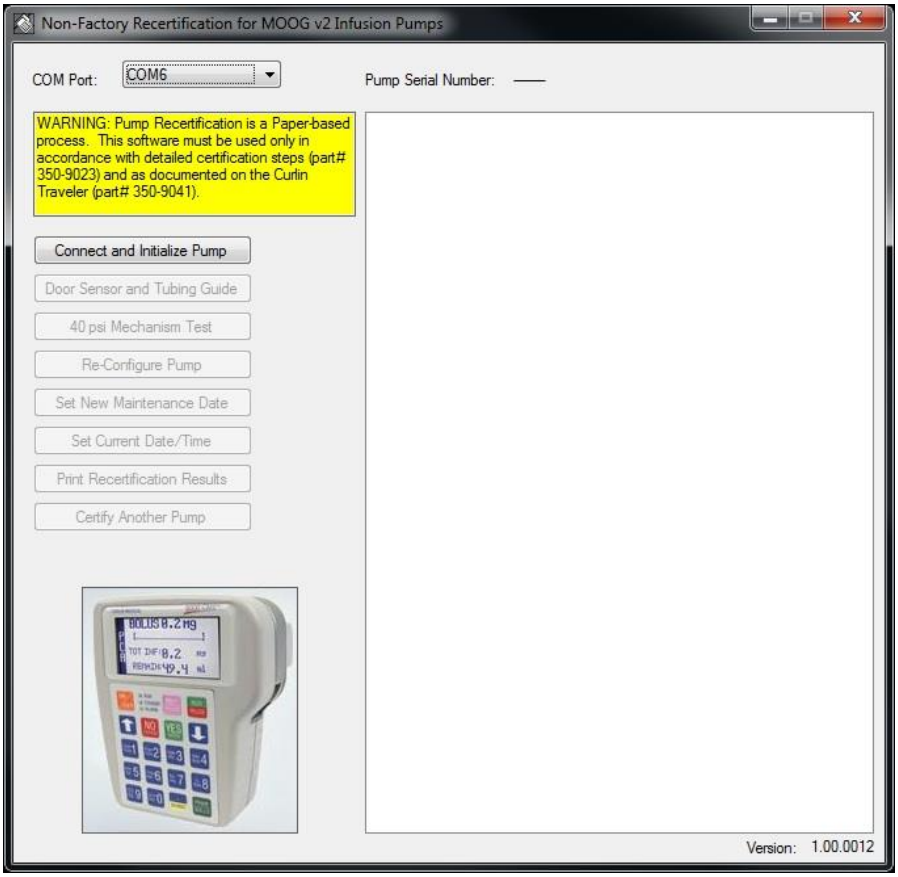
Non-Factory Recertification Software Version Rev R5

AS-45914

If you are servicing 6000 series or PainSmart pumps with pump software v2.01 or higher, you will need to install the NFR software with part number AS-45914 (referred to here as v2). Obtain a copy of the software and install it into your PC.

The NFR software v2 is different from the PRU in that it does not need a registration code to configure. Once you have finished installing the software, you are ready to use it to perform the NFR procedures.

The NFR v2 also looks different from the PRU. Double click on the icon MOOG-NFR V2 to open it. You will see the image below.

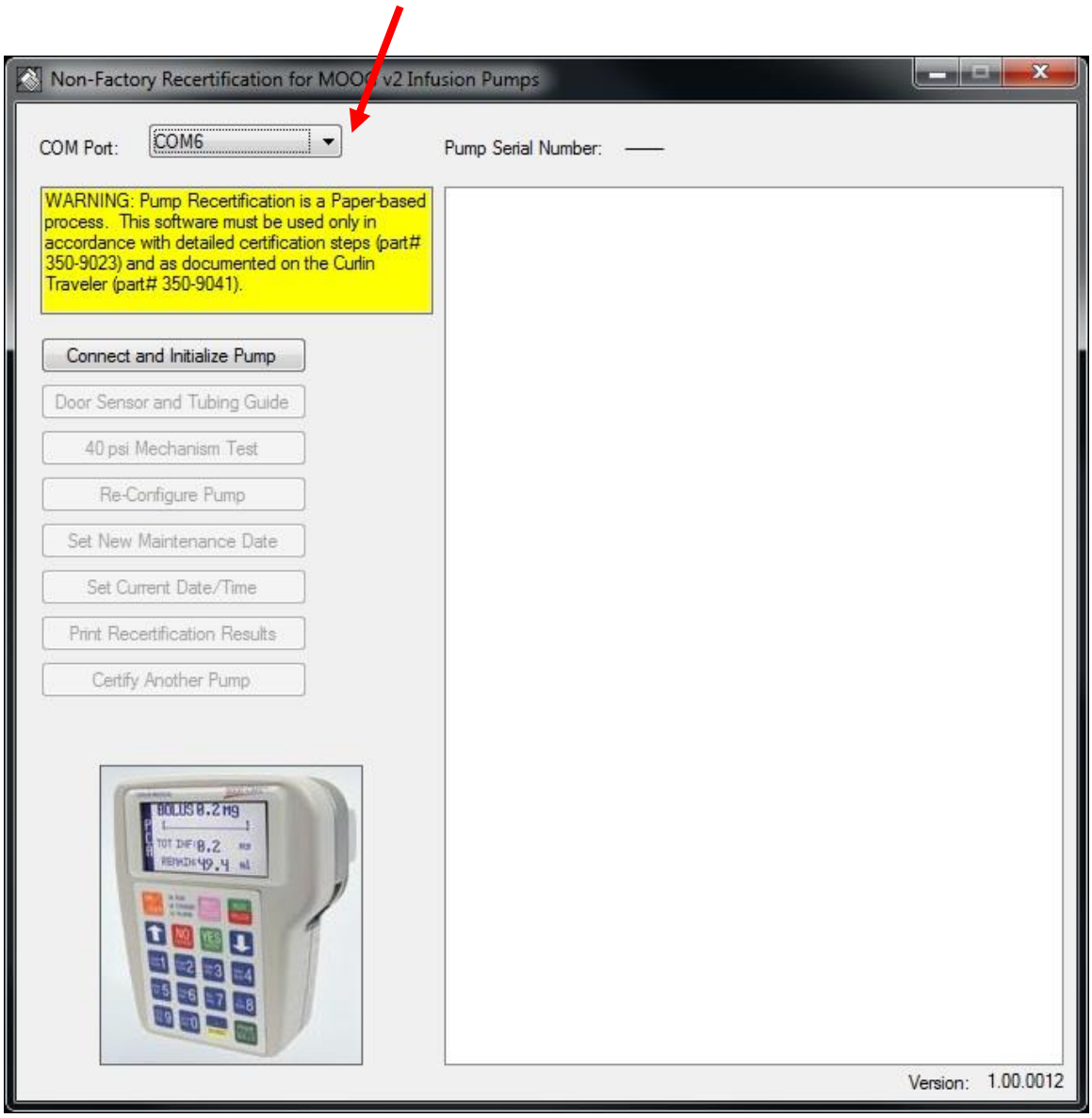

Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port:
COM6
Pump Serial Number:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump
Door Sensor and Tubing Guide
40 psi Mechanism Test
Re-Configure Pump
Set New Maintenance Date
Set Current Date/Time
Print Recertification Results
Certify Another Pump
Version: 1.00.0012

Non-Factory Recertification Software v2

After installing the NFR software, make sure your PC has a serial port for the data interface cable (340-2011). If you don't you will need to prepare a serial-to-USB adapter. Although the Required Equipment shows the **Keyspan USB-Serial Adapter**, you do not have to use the same brand of adapter. And if your PC already has a serial port, you will not need an adapter at all.

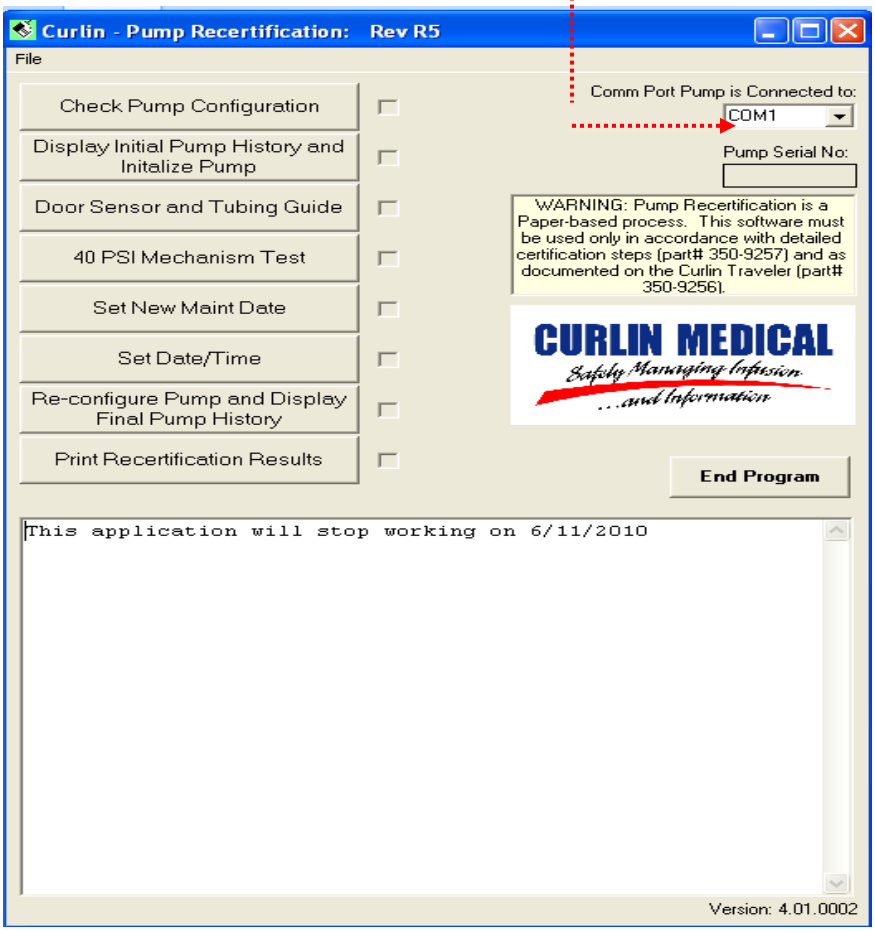
If yo need an adapter, you will first need to install its driver software. Once that is done, find the correct COMM PORT on the drop down options in the COMM PORT window in the NFR software. Select the correct COMM PORT.

Set the correct COMM PORT.


Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port:
COM6
Pump Serial Number:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump
Door Sensor and Tubing Guide
40 psi Mechanism Test
Re-Configure Pump
Set New Maintenance Date
Set Current Date/Time
Print Recertification Results
Certify Another Pump
Version: 1.00.0012

Comm Port window for NFR Software v2

Set the correct COM port.


Curlin - Pump Recertification: Rev R5
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 6/11/2010
Version: 4.01.0002

Comm Port Window for NFR Software Rev R5.

With the correct COMM PORT selected, you are ready to begin the NFR Procedures. The next chapter walks you through the steps, for both the Rev R5 version and the newer v2.

Addendum for Windows 7

If your PC has Windows 7, you will need to run the programs as the administrator. After installing the software, you will find the icons on your monitor for the two NFR Software. To run these as the administrator, follow the steps below:

(1) Move your mouse so that the cursor is on top of one of the icons.

(2) Right click on the icon. A drop down menu will appear, with "Properties" at the very bottom.

(3) Left click on the "Properties". A table will appear. One of the choices on the top will be "Compatibility".

(4) Left click on "Compatibility" to reveal several choices. One of the choices will be the "Privilege level", below which is a box saying "Run this program as an administrator".

(5) Check the box beside the option "Run this program as an administrator." Then click OK.

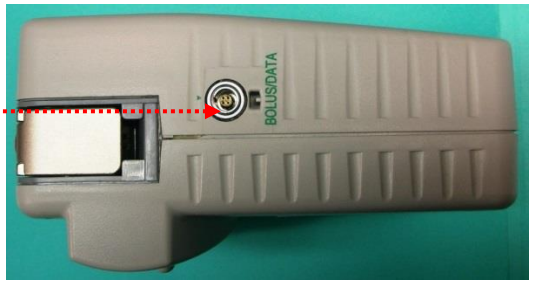
(6) Repeat the same steps for the other NFR icon.

(7) Your PC is now ready to run the NFR programs under Windows 7.

Chapter 4: The NFR Procedure

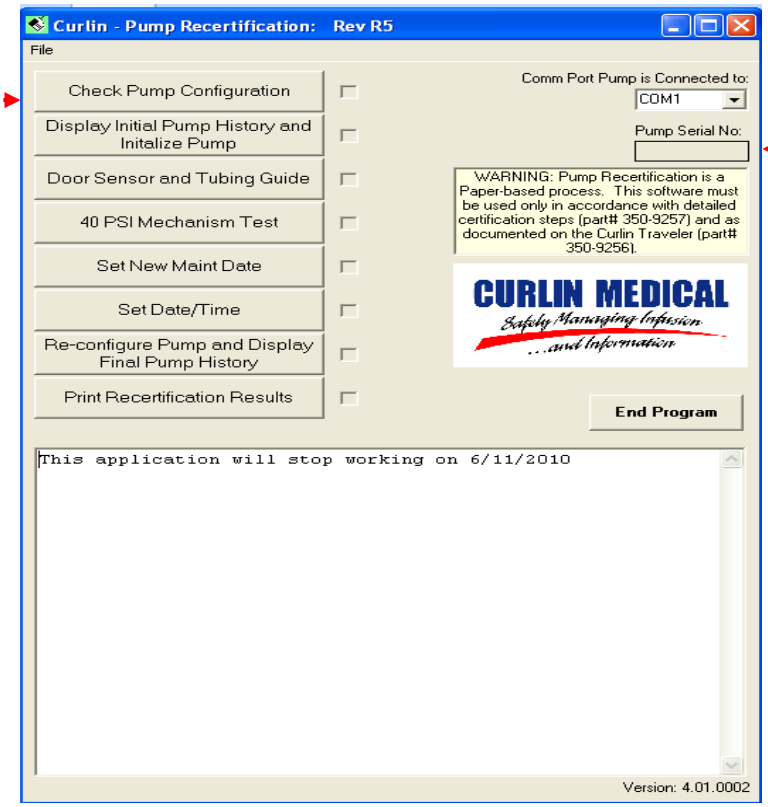
Connect the Pump to the PC

Using the Data Interface cable for PC (340-2011), connect the PC Serial Port connector to the Pump Bolus/Data connector of the pump to be recertified. Turn the pump ON.



Check Pump Configuration

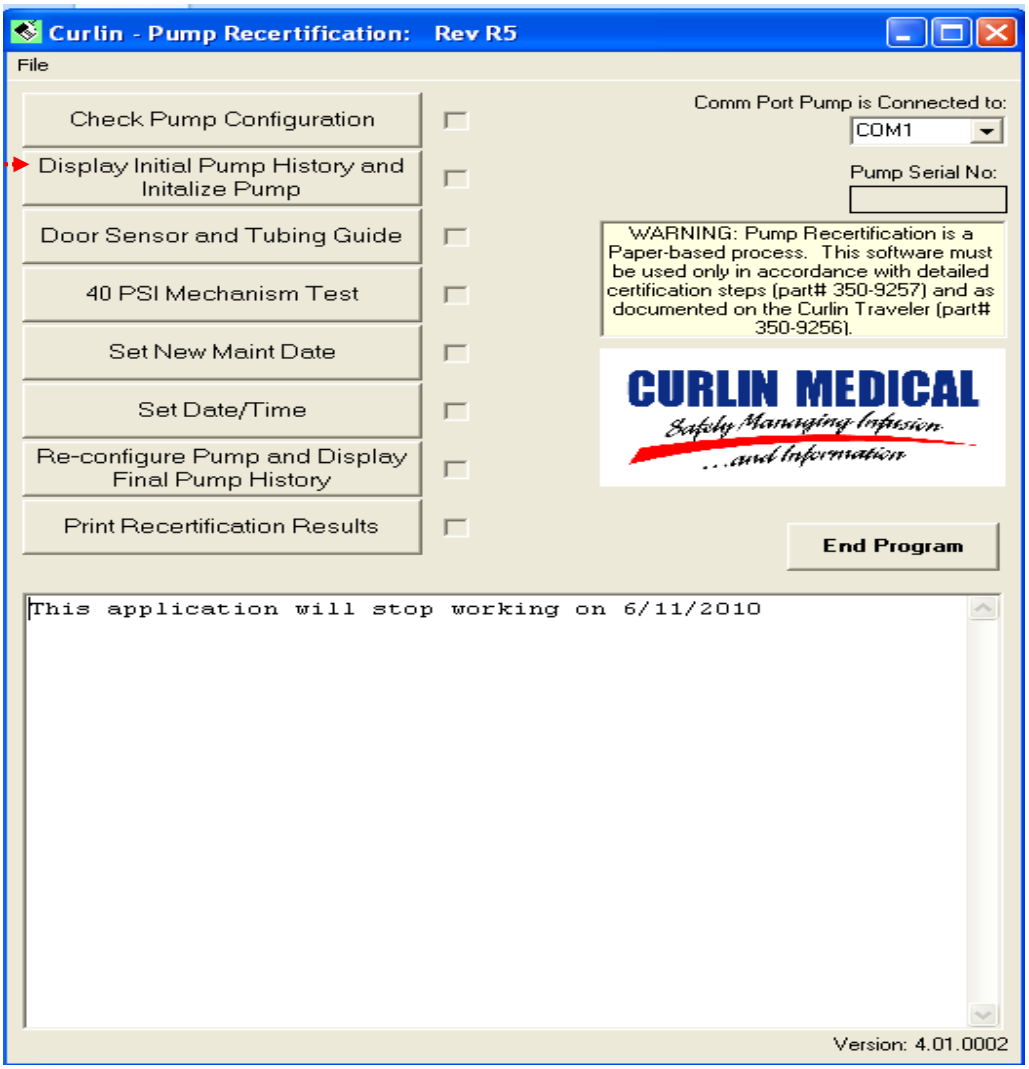
From the PRU, select "Check Pump Configuration". Observe the "Pump Serial Number" is displayed on the PRU screen. (Note: if pump is a 2000 Plus, the PRU will require technician to cause the pump to enter the BIOMED Setup menu by entering the Clinician Code 94629. In addition, the technician must manually enter the pump Serial Number. If pump is a 4000 Plus, the PRU will require technician to cause the pump to enter the BIOMED Setup menu by entering the Clinician Code 94629.) When the serial number of the pump is displayed, the pump is ready to be processed.


Curlin - Pump Recertification: Rev R5
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 6/11/2010
Version: 4.01.0002

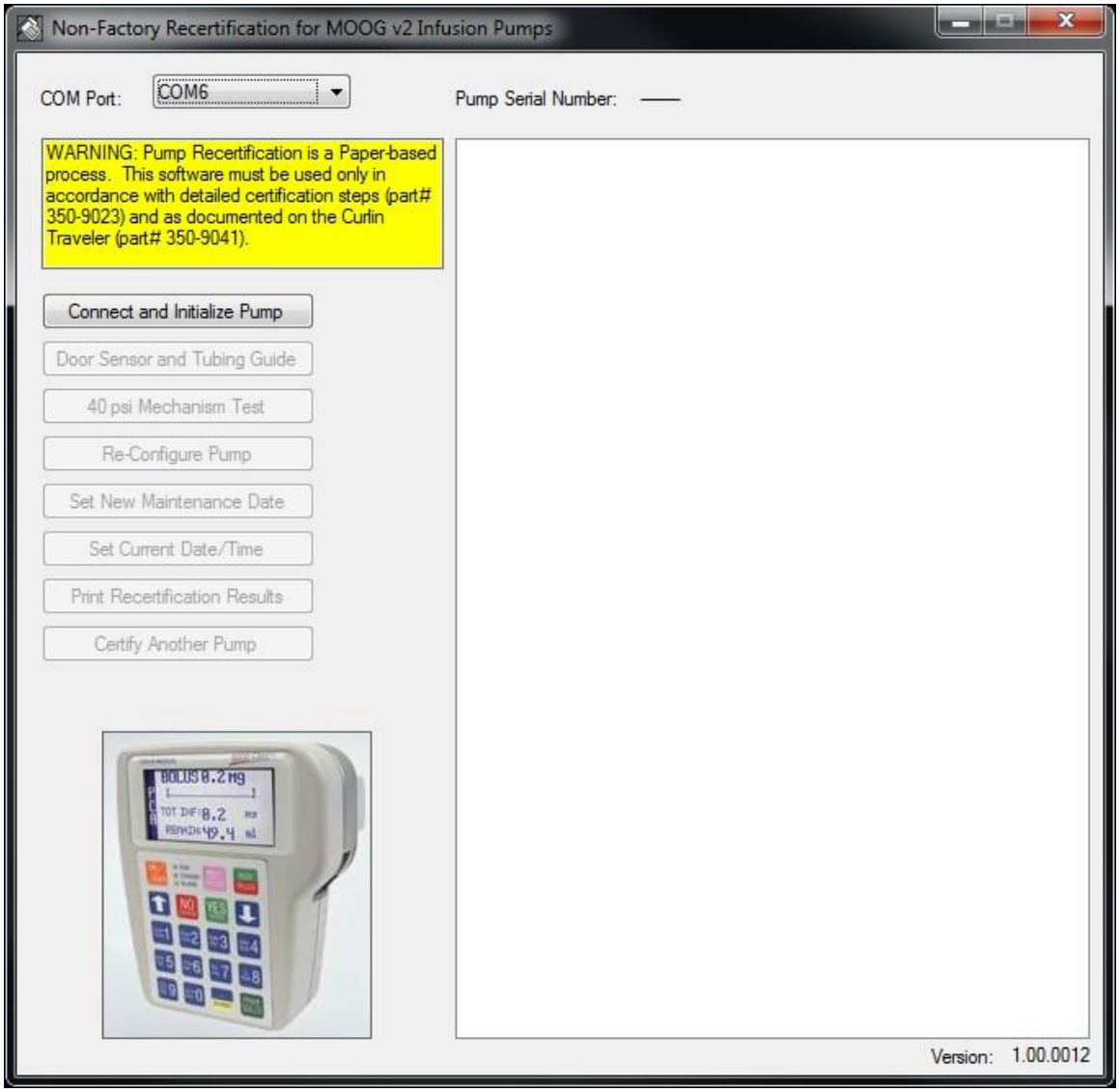
Display Initial Pump History and Initialize Pump

From the PRU, select "Display Initial Pump History and Initialize Pump". Observe the Pump Hx being downloaded from the pump.

Note: If the pump is an E-Config (PainSmart), the PRU will initialize the pump. So wait until initializing has finished.


Curlin - Pump Recertification: Rev R5
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 6/11/2010
Version: 4.01.0002

(Note: The pump history will print during the last step "Print Recertification Results". If you are using the NFR Software v2, press the "Connect and Initialize Pump" to begin the NFR process for a 6000 Series or Painsmart pump. This single step combines the first two steps in the PRU. This will populate the window on the right hand side with the abbreviated pump history. Confirm that the serial number is correct, and check the pump history for any recent Malfunctions. The v2 screenshot is shown on the following page.)


Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port:
COM6
Pump Serial Number:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump
Door Sensor and Tubing Guide
40 psi Mechanism Test
Re-Configure Pump
Set New Maintenance Date
Set Current Date/Time
Print Recertification Results
Certify Another Pump
Version: 1.00.0012

Screenshot of NFR Software v2. Connect and Initialize button ready to press.

When the self-recertification process is executed, **the pump is initialized in order to set it into a state where all tests can be run**. In some cases, if the process is interrupted at critical moments, the pump will not go through the process to set it back to its original configuration. For this reason, the pump's initial configuration data is stored in a file and so the pump can be reconfigured even in the event of an interruption in the process.

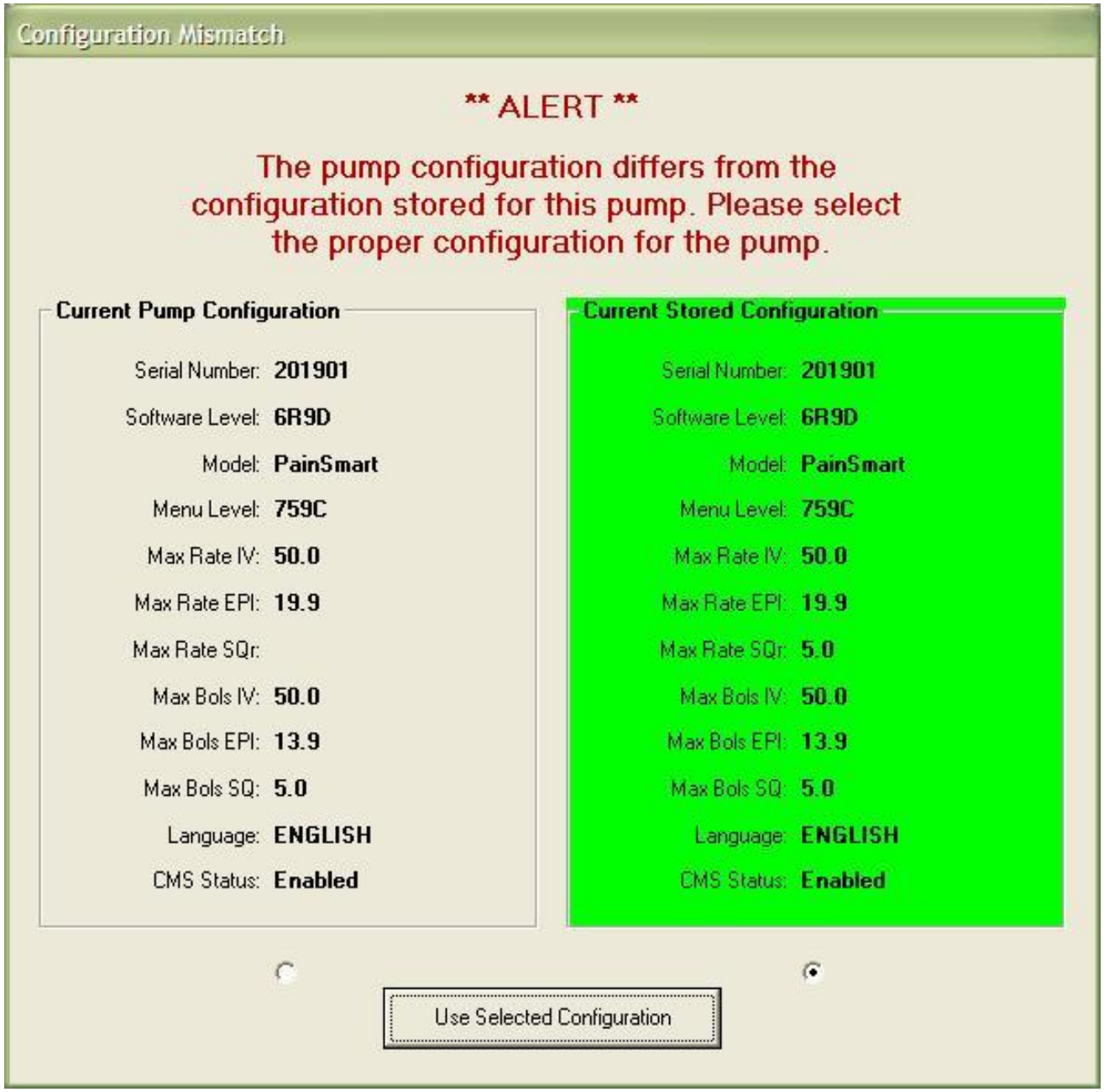
When the pump's current configuration differs from the file's configuration for the pump, a window will appear offering the option to choose the desired configuration (see below). All pertinent data will be presented to facilitate an informed decision regarding the intended final configuration of the pump. The window will default its choice to the left side. There are two possibilities when this event may occur. The first is when a recertification process is interrupted (like by a power outage, for example, or when the technician needs to leave for an emergency) so that it was not finished, but can be continued later. The second case is when a pump fails to reconfigure because of a defect, and a new pump is put in place for recertification.

If the pump fails to finish the NFR process because it was interrupted, when you are ready to continue, reconnect the pump to the software and press the first button (connect and initialize). The window below will appear; because the recertification process is being continued after it was interrupted, select the right side so that it is highlighted before pressing the "Use Selected Configuration" button. This makes sure that the original configuration of the pump is kept in storage until the recertification process is done.

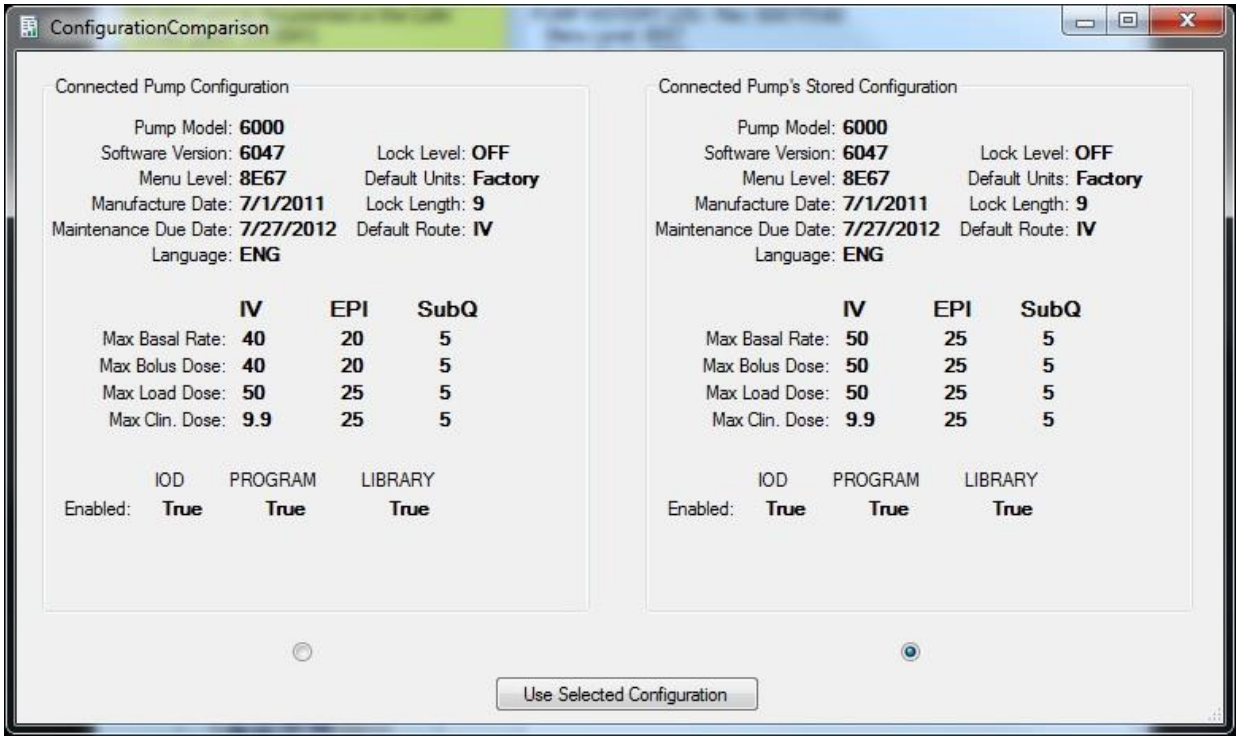
Sometimes a recertification fails in the middle of the process (in the event of failing tests or a crucial error code), and the pump is not able to be set back to its original configuration. In a case like this, the defective pump is disconnected and prepared to be sent to a service facility. When a new pump is connected to the NFR software after this, the software still has the original configuration of the defective pump stored, and the new pump will be detected to have a mismatch in configuration, and the window below will also pop up. In this instance, select the left side of the window, which represents the "Current Pump Configuration" so that it is highlighted, and then press the "Use Selected Configuration" button. The software then replaces the stored configuration with the new pump's configuration, and the recertification for this new pump can be started.

Care must be exercised when this window pops up. Choosing the wrong side of the window will cause the loss of the pump's original configuration, and when that happens, the only way to retrieve the original configuration is to send the pump back to MOOG for reconfiguration.

The PRU will display the window as "Configuration Mismatch" (see the screenshot on the next page) with an accompanying "ALERT" on top of the display. The V2 software will display the window as "Configuration Comparison" and will not have the alert, and will not highlight the chosen side (see the screenshot on the following page).



Configuration Mismatch window for Rev R5.



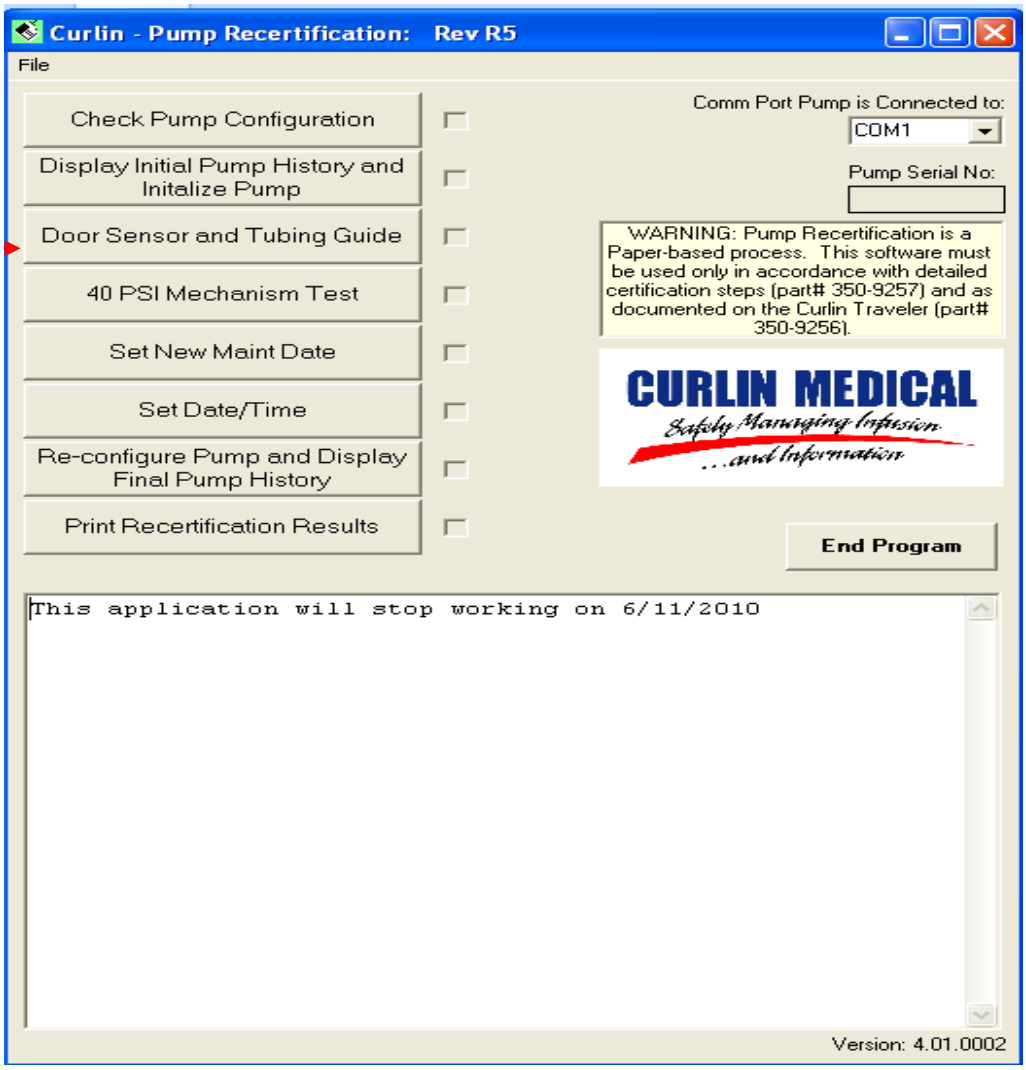
Configuration Comparison window for v2

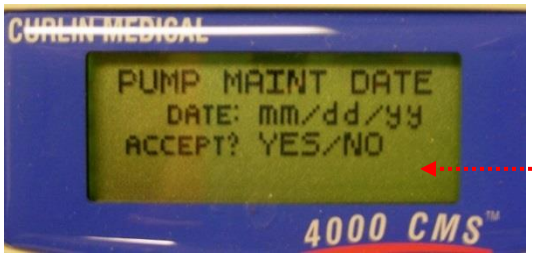
Even though the values on both sides may seem identical, always be aware which side represents the **original configuration of the pump being recertified**, and choose that side. Choosing the wrong side will mean loss of original configuration, and the NFR software is not equipped to retrieve a pump's original configuration once it is lost. **Choose carefully.**

Once the pump is successfully initialized, record that on the NFR Traveler. If the mismatch window showed up, include that in the comments. After initializing the pump, prepare for the Door Sensor and Tubing Guide test, which follows.

TEST 1 - Door Sensor and Tubing Guide

From the PRU, select "Door Sensor and Tubing Guide". Once the pump enters the Factory Menu, an Alert on the pump will occur. Execute the following key sequence on the pump:


Curlin - Pump Recertification: Rev R5
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 6/11/2010
Version: 4.01.0002



1 DOOR SENSOR and TUBING GUIDE

a. From the NFR Software (Moog P/N 350-7021) Press the Door Sensor and Tubing Guide Button

b. Once the pump enters the Factory menu the following key sequence on the pump.

c. Press the DOWN ARROW key once to arrive at the ACCEPT? Field.

d. Press NO key once to arrive on the factory menu.
e. Scroll up to DISP DOOR SEN and press YES.
f. Insert the Tubing Guide Gauge (PN 340-5056) into the pump tubing guide cavity

g. Close and latch the door.
h. Verify the screen says DOOR CLOSED.
i. Open the door and verify the screen says DOOR OPEN.
j. Remove the Tubing Guide Gauge and close the door.
k. Verify the screen says DOOR OPEN.
l. Record all results on the Non-Factory Service Traveler
m. Arrow down once to exit DISP DOOR SEN and reenter factory menu.
n. Scroll down to the very bottom and push YES key to exit the factory menu.
o. Scroll down to the BIOMED SETUP section of the pump, and input the clinical access code. If it requires a 9-digit code, input 9999 followed by the clinical code 94629, and if the pump only requires a 5-digit code, input the clinical code 94629.

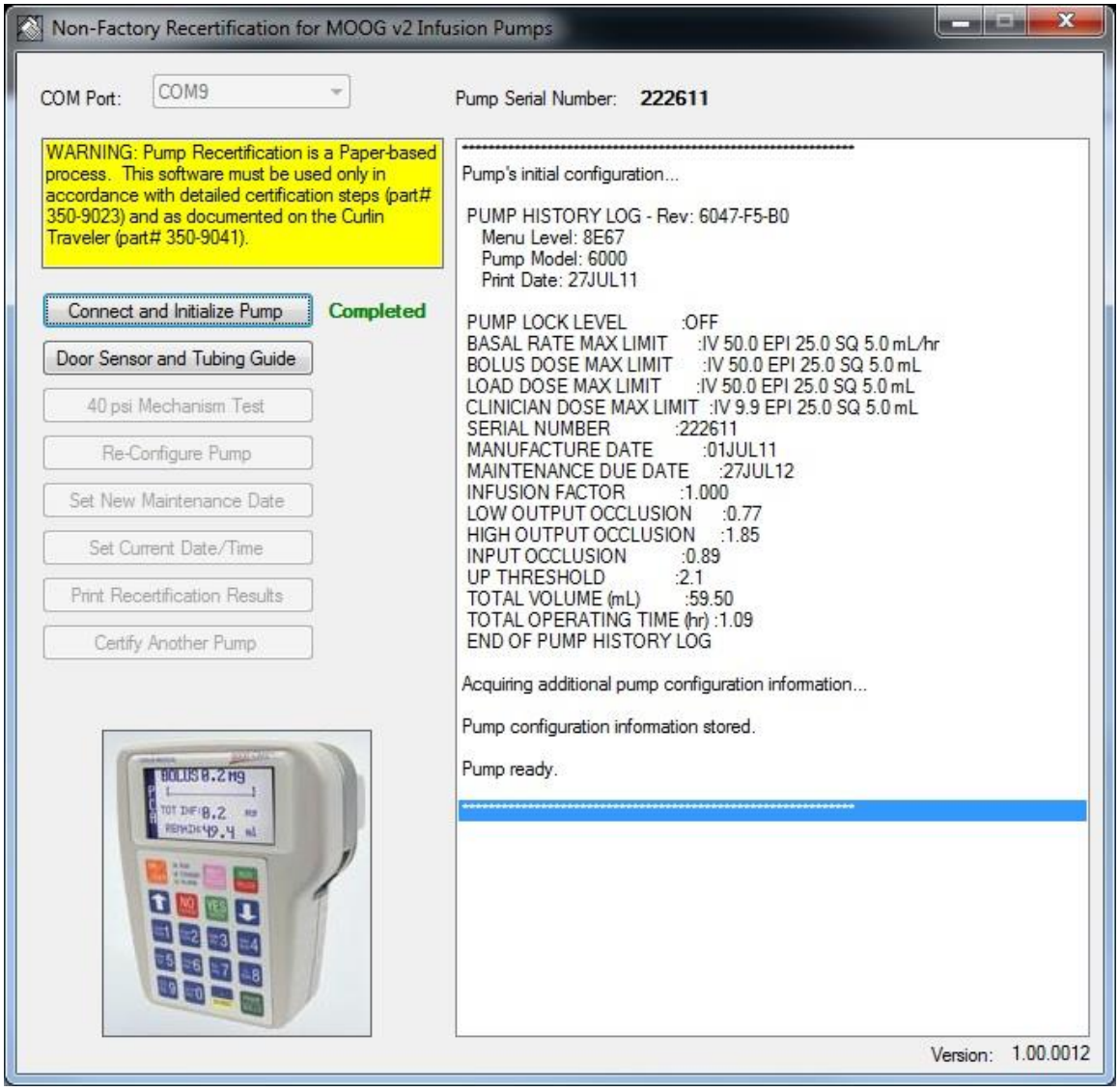
9-digit example	5-digit example
9999-94629	94629

p. Scroll down to the DATE AND TIME and press YES. Press YES on all the fields. Afterwards, press YES on "DONE?".

The pump is now in default mode. All rates and volumes are available for testing purposes. See the following chapters for directions on properly evaluating the pump and verifying any service done.

The data cable can now be disconnected in order to evaluate and service the pump.

(Note: The screenshot for the software V2 is shown on the next page. Follow the same steps above to perform Test 1).


Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port:
COM9
Pump Serial Number: 222611
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump
Completed
Door Sensor and Tubing Guide
40 psi Mechanism Test
Re-Configure Pump
Set New Maintenance Date
Set Current Date/Time
Print Recertification Results
Certify Another Pump
Pump's initial configuration...
PUMP HISTORY LOG - Rev: 6047-F5-B0
Menu Level: 8E67
Pump Model: 6000
Print Date: 27JUL11
PUMP LOCK LEVEL :OFF
BASAL RATE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL/hr
BOLUS DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
LOAD DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
CLINICIAN DOSE MAX LIMIT :IV 9.9 EPI 25.0 SQ 5.0 mL
SERIAL NUMBER :222611
MANUFACTURE DATE :01JUL11
MAINTENANCE DUE DATE :27JUL12
INFUSION FACTOR :1.000
LOW OUTPUT OCCLUSION :0.77
HIGH OUTPUT OCCLUSION :1.85
INPUT OCCLUSION :0.89
UP THRESHOLD :2.1
TOTAL VOLUME (mL) :59.50
TOTAL OPERATING TIME (hr) :1.09
END OF PUMP HISTORY LOG
Acquiring additional pump configuration information...
Pump configuration information stored.
Pump ready.
Version: 1.00.0012

NFR Software v2 showing pump is ready for Test 1.

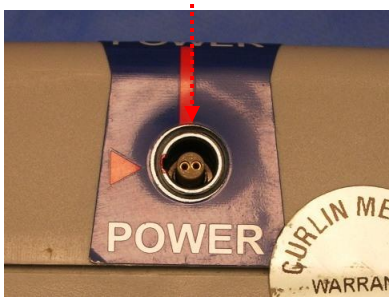
Chapter 5: Pump Evaluation

1 PHYSICAL EXAMINATION

1) Examine the outer surface of the pump for damage. Pay special attention to the areas noted below.

2) Check the door operation. Make sure it opens and closes easily and shows no signs of bending. Check to see if the door comes in contact with the frames, and if it's too loose or too tight. NOTE: Functional tests will be performed later to verify door platen shape.

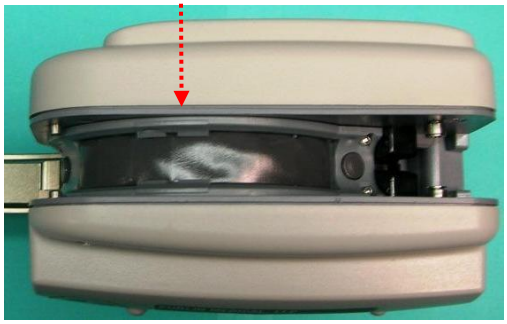
3) Inspect the LEMO plug areas for signs of damage. Some pumps may need you to examine under the labels if any damage is suspected.



4) Inspect the battery door area for damage. Verify the door can be opened and closed easily. Look inside the battery compartment and check battery springs and battery contacts for damage.

5) Verify all labels are in good shape and easily read.

6) Open the door and examine the surface of the motor assembly for damage. Look at the seal for tears and punctures and examine the housing for cracks.



7) Chapter 7 will describe how to replace any components found damaged during the physical examination.

2. FUNCTIONAL EXAMINATION

- REQUIRED EQUIPMENT

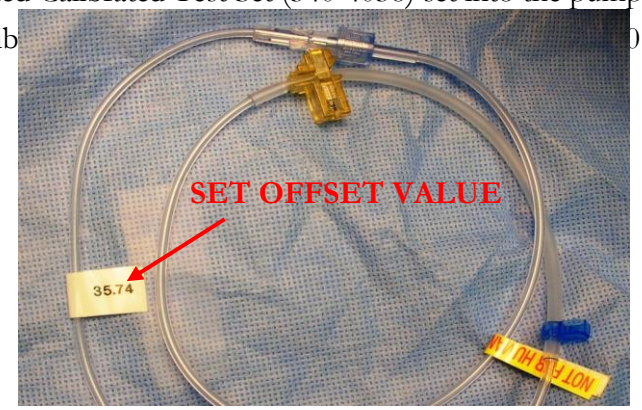
The following equipments are required to perform the function test on the pump:

a. Scale – Minimum resolution 0.01 g. Minimum capacity 250 g.
b. Digital pressure gauge (-30 to 60 psi)
c. Moog Test Admin Sets (Moog P/N: 340-4123-02).
d. **Calibrated** Test Set (Moog P/N: **340-4038**).
e. Tubing Guide Gauge (340-5056)
f. 2 Beakers. Minimum capacity 200 ml.
g. Water – Distilled water (specific gravity 0.998).
h. 18 Gage Needle (P/N 52281).
i. AC Adapter (Moog P/N: 340-2026 / 340-2022 / 47684).
j. Bolus Cable (Moog P/N: 340-2005 / 360-2005).
k. 2 C-cell Batteries.
l. Digital Timer
m. Non-Factory Recertification Software, NFR (Moog P/N: 350-7021).
n. Non-Factory Service Traveler (Moog P/N: 350-9041).
o. Data Interface Cable for PC (Moog P/N: 340-2011).
p. Personal Computer with Microsoft Windows: 2000, or XP.
q. Calculator
r. Head height is 12" (see diagram pg. 30)

3.TEST 2 - VOLUME ACCURACY TEST

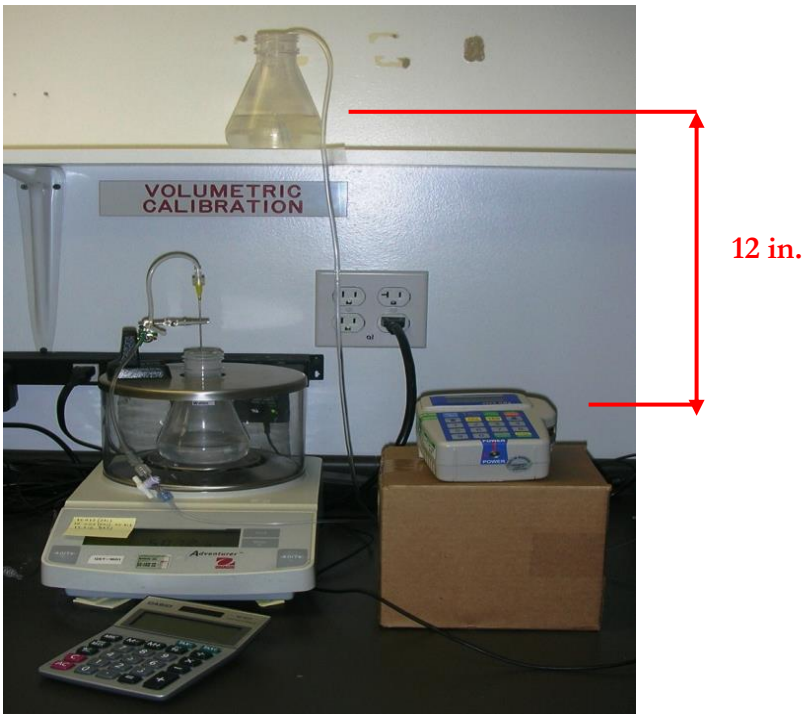
a. Install a primed Calibrated Test Set (340-4038) set into the pump and close the door.

NOTE: Calib 0 times before being discarded.



b. Connect the output side of the administration set to an 18 Gage Extended needle and place the needle output in beaker of water so that its output is below the water level.

c. Connect the input side of the administration set to a suitable reservoir. Use an extended tubing as needed. Maintain a 12-inch head height between the reservoir water level and the top of the pump at the beginning of each test.



d. Perform a Continuous therapy volume check. Enter PROGRAM and select CONTINUOUS among the choices. When prompted, input the clinician code (9999-94629 or 94629 as needed). Input the following data for the therapy:

Pre Rx::

UNITS:	ml
DELAY:	OFF
Titrate:	OFF
NEXT?	YES

Prescription:

BAG VOL:	100	ml,
VOL TBI:	10	ml
RATE:	125	ml/hr,
TIME:	0:04	HH:MM
KVO Rate:	0.1	ml/hr
DONE?	YES	

When infusion completes, calculate the volume infused using the following equation. Use 2 digits of precision.

Calculated Value = (Actual Amount Infused x 35.0) / Set Offset Value

e. The calculated value should be 10 ml (+/-0.20 ml). Record the Calculated Value on the Non-Factory Service Traveler (350-9041). In the comments, write down the Set Offset value of the calibrated set.

f. If the volumetric calibration is out of spec, perform Volume Accuracy Calibration by following the procedure described in Chapter 8(Pg. 82).

4. CHECK ALL SAFETY SYSTEMS

a. Connect the pump to the AC Adapter. Put two C-cell batteries in the pump as well.

b. Connect the PC Serial Port connector to Bolus/Data connector of the pump to be serviced. Turn on the pump and select "Door Sensor and Tubing Guide" from the NFR Software. Press "Down Arrow" once and then "No" on the pump when instructed by the PC.

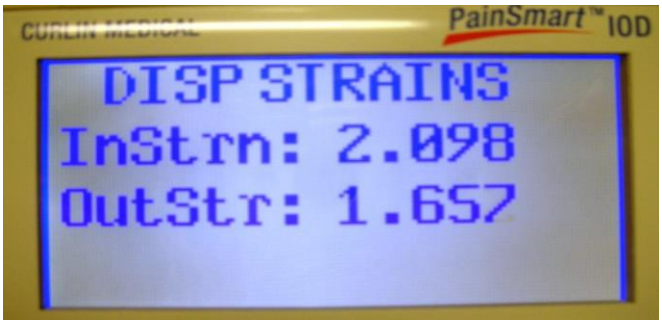
c. Scroll **UP** to DISP STRAINS then press the "YES/ENTER" key.

d. Install a dry Moog Test Administration Set (340-4123-02) into mechanism and close latch.

e. Start a timer for two minutes.

f. Observe and record the voltage readout for the Output Strain Beam (OutStr:) and Input Strain Beam (InStrn:) after 2 minutes.

g. After 2 minutes, the Input Strain Beam voltages should read 2.100 volts (±0.300 volts) and Output Strain Beam voltages should read 1.700 volts (±0.300 volts). If the Strain Beams are out of spec, perform Pressure Sensor Baseline Calibration by following the procedure described in Chapter 8 (Pg. 85.)



h. Press Yes/Enter key to exit the Strain beam screen and scroll to the bottom and select YES.

i. Check the Keypad by programming pump to do a Continuous Therapy: Enter PROGRAM and select NEW PROGRAM. When prompted, input the clinician code (94629 or 9999-94629). Input the following therapy:

Pre Rx:		
UNITS:	ml	
DELAY:	OFF	
Titrate:	OFF	
NEXT?	YES	
Prescription:		
BAG VOL:	8765	ml
VOL TBI:	42.1	ml
RATE:	390	ml/hr
TIME:	0:06	HH:MM
KVO Rate:	0.1	ml/hr
DONE?	YES.	

j. Install a primed set into the pump. (Moog P/N 340-4123-02)

k. Place the tubing ends into a beaker of water.

l. Start the pump running.

m. With infusion in progress open the door latch and observe ALARM DOOR OPEN OR SET NOT INSTALLED.

n. Remove the administration set from the pump and reinstall it so that the flow stop and tubing guide are not in the pumping chamber. Close the door latch and start an infusion by pressing the RUN key. Observe ALERT DOOR OPEN OR SET NOT INSTALLED will occur.

o. Reinstall the administration set properly and resume the infusion. With the pump running lift the inlet side of the administration set out of the reservoir and allows air to be infused. Once the air reaches the AIL detector an ALARM AIR IN LINE will occur.

p. Place the tubing inlet back in the reservoir and prime out the air. Prime the air out of the administration set and Resume the infusion.

q. Pinch off the tubing on the Input Side of the pump to cause an Up Occlusion. Verify the pump alarms correctly. Pause and Resume the infusion.

r. Pinch off the tubing on the Output Side of the pump to cause a Down Occlusion. Verify the pump alarms correctly. Release the pinched off tubing and observe the pump automatically restarts.

s. With the pump running observe the Vol INF (volume infused on the run screen) and unplug the AC Adapter from the pump (if it is plugged in). Open the battery door and remove a C-cell battery. Observe the Auxiliary Alarm System is activated. With the battery still out of the pump, press the On/Off button to turn off the alarm.

Auxiliary Alarm Light on.

t. Plug the AC Adapter in its proper place and turn on the pump. Resume the therapy and confirm that the infusion continues where it stopped due to Auxiliary Alarm occurrence.

u. PAUSE the program and scroll down to NEW PROGRAM to begin a new therapy. Press YES and again to "YES to New Program". Choose PCA among the options.

v. Program and run a 9.9ml/hr PCA therapy with a 1 ml bolus.

Pre Rx:

UNITS:	ml
ADMIN Rt:	IV
LOAD DOSE:	0 ml
medLMTS:	OFF
NEXT?	YES

Prescription:

BAG VOL:	50	ml
BASL RATE:	9.9	ml/hr
Pt. BOLUS:	1	ml
BOLS INT:	10	MIN
# BOLS/hr:	5	
DONE?	YES.	

w. Listen to the pump running for a couple of minutes. Notice that once per peristaltic cycle the motor races to perform a Speed Up cycle.

x. Connect a Bolus Cable (P/N 360-2005) to the connector on the side of the pump. Press the Bolus Switch on the Bolus Cable. Observe the word BOLUS appears on the top line of the LCD display (flashing).

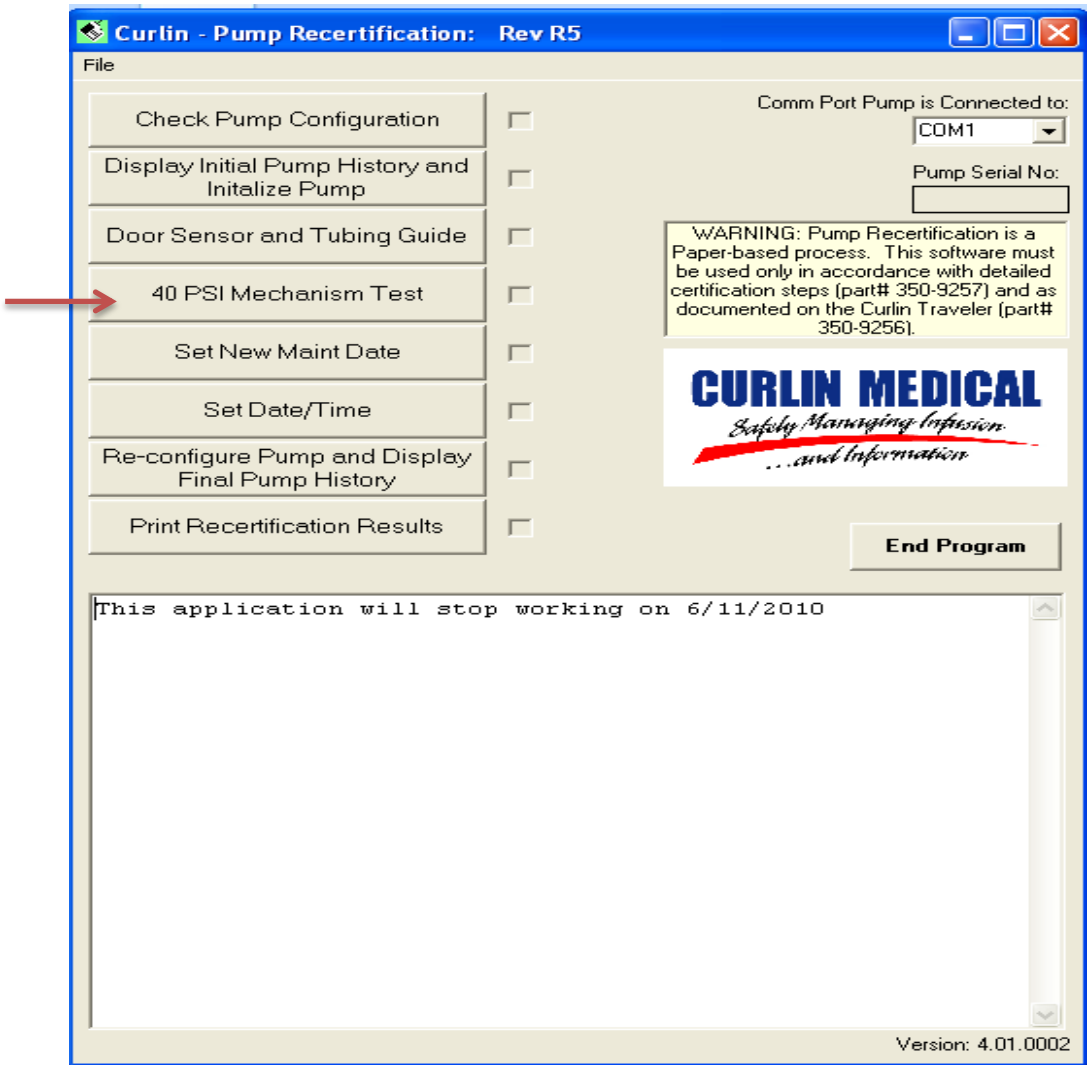
y. Record all test results on the Non-Factory Service Traveler (350-9041).

z. Any step that does not work as described above means a failed test. If any of the tests failed, perform appropriate service/repair or send pump back to Moog.

5. TEST 3 - 40 PSI BACK PRESSURE TEST

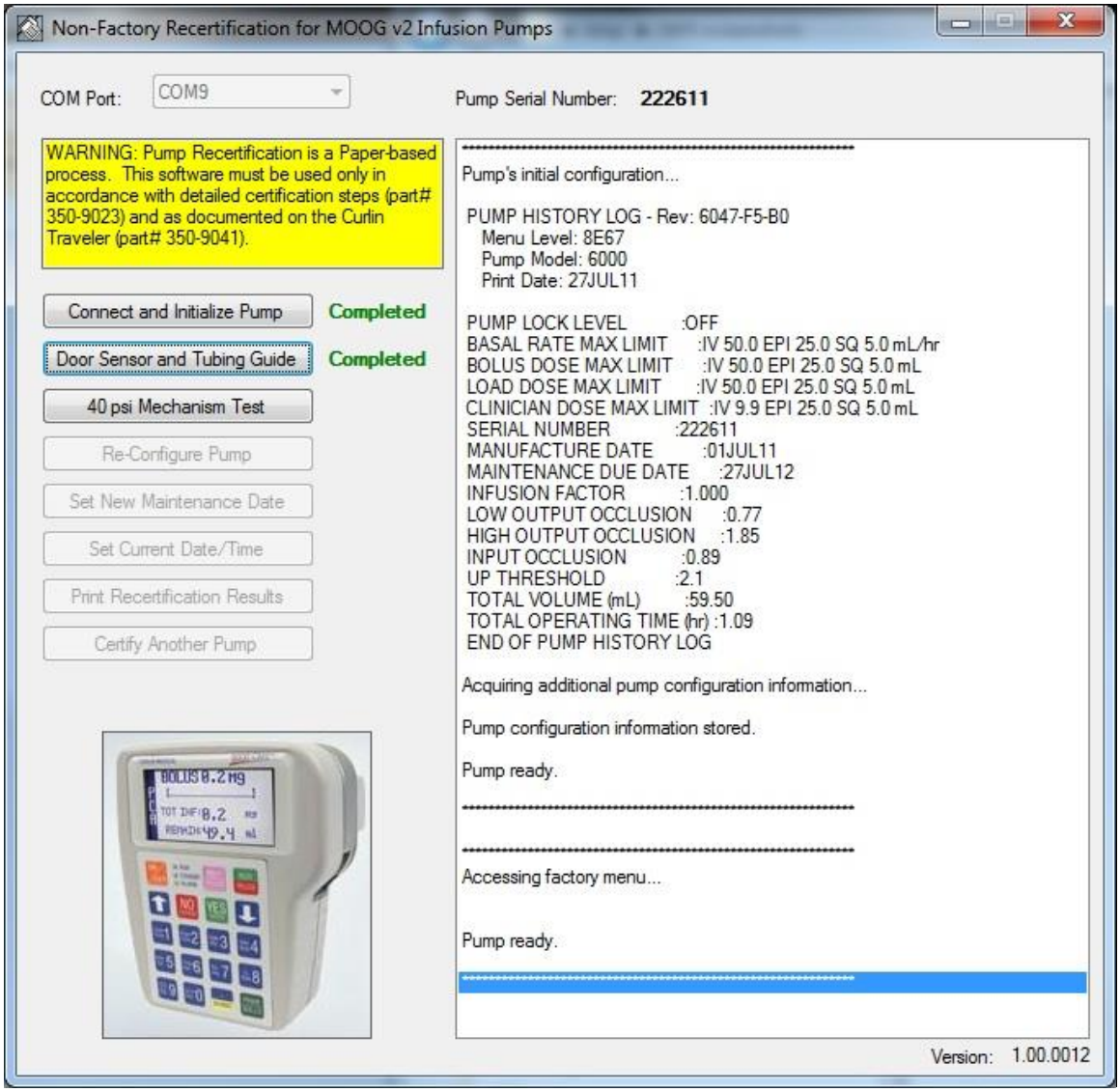
a. Connect the pump to the AC Adapter.

b. Connect the PC Serial Port connector to Bolus/Data connector of the pump to be serviced. Turn on the pump and Press the "40 PSI Mechanism Test" button. This will disable all the alarms and malfunctions on the pump. For the Rev R5, the screenshot below shows the button. **If you are using the v2 software, a "COMM TIMEOUT" Alarm will trigger after the alarms are disabled.** Clear this alarm before continuing (see next page for screen shots).

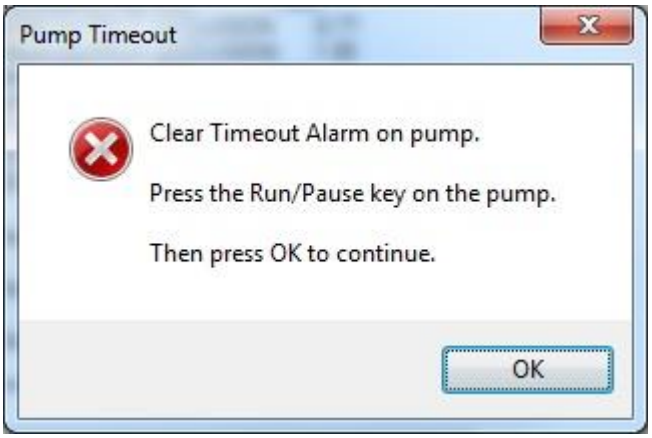

Curlin - Pump Recertification: Rev R5
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 6/11/2010
Version: 4.01.0002

c. Insert a primed Moog Test Administration Set (Moog P/N 340-4123-02). *(Note: this administration set does not need to be a new set; However, once used for the 40 PSI Mechanism test, this set may only be used hereafter for subsequent 40 PSI Mechanism tests.)*

d. Connect a pressure gauge capable of measuring at least 50 PSI to the output/patient side of the primed administration set (Moog P/N 340-4123-02)


Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port:
COM9
Pump Serial Number: 222611
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump
Completed
Door Sensor and Tubing Guide
Completed
40 psi Mechanism Test
Re-Configure Pump
Set New Maintenance Date
Set Current Date/Time
Print Recertification Results
Certify Another Pump
Pump's initial configuration...
PUMP HISTORY LOG - Rev: 6047-F5-B0
Menu Level: 8E67
Pump Model: 6000
Print Date: 27JUL11
PUMP LOCK LEVEL :OFF
BASAL RATE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL/hr
BOLUS DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
LOAD DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
CLINICIAN DOSE MAX LIMIT :IV 9.9 EPI 25.0 SQ 5.0 mL
SERIAL NUMBER :222611
MANUFACTURE DATE :01JUL11
MAINTENANCE DUE DATE :27JUL12
INFUSION FACTOR :1.000
LOW OUTPUT OCCLUSION :0.77
HIGH OUTPUT OCCLUSION :1.85
INPUT OCCLUSION :0.89
UP THRESHOLD :2.1
TOTAL VOLUME (mL) :59.50
TOTAL OPERATING TIME (hr) :1.09
END OF PUMP HISTORY LOG
Acquiring additional pump configuration information...
Pump configuration information stored.
Pump ready.
Accessing factory menu...
Pump ready.
Version: 1.00.0012

Once the pump alarms Comm Timeout press the Run/Pause button on the pump, and then click OK on the NFR software.



These figures are for the NFR Software 45914 (v2). The pump timeout window appears after the alarms are disabled.

e. Set up the pump as shown below.

f. Program the pump with the following Continuous infusion:

Pre Rx:

UNITS:	ml	
DELAY:	OFF	
Titrate:	OFF	
NEXT?	YES	

Prescription:

BAG VOL:	200	ml
AMT TBI:	100.0	ml
RATE:	20	ml/hr
TIME:	5:00	HH:MM
KVO Rate:	0.0	ml/hr
DONE?	YES	

Option:

AIR Sens:	0.1	ml

g. Place the inlet side of the administration set into the water reservoir as shown on the setup above, and prime the air out of the administration set.

h. Zero the pressure gauge and start the infusion. With the output side occluded, pressure will build up on the pressure gauge.

i. While the pump is running observe the pressure gauge. Pressure will build with each peristaltic cycle. Pump must be able to pump more than 40 PSI. In addition, prior to reaching 40 PSI, pumping pressure shall not drop more than 10 PSI. Stop the infusion after 40 PSI pressure has been attained.

j. Document the result on the Traveler.

k. If the pump does not pass the first time, you may do a retest.

If the pump does not meet these criteria:

- Did you set up the test so that the pressure gauge measures the downstream pressure? If not, refer to the figure on the preceding page for the test setup.
- Did you prime the set? If not, prime the set until there is no air bubble inside the test set.

If you answered yes for the above questions and the pump still failed to attain specified pressure or suffered more than 10 psi drops in pressure, the pump must be serviced by a trained service technician.

6. TEST OF PRESSURE SENSORS CALIBRATION

a. Turn the pump OFF and back ON again.

b. Install a primed Moog Test Administration Set (340-4123-02) into mechanism.

c. Test Output Strain Beam for 8 and 18 PSI Thresholds:

i. Connect the Digital Pressure Gage and a 3-way valve to the downstream side of the Moog Test Admin Set such that the pressure gage can read the down occlusion pressure.

ii. Program pump to do a New Continuous Therapy:

Pre Rx:

UNITS:	ml
DELAY:	OFF
Titrate:	OFF
NEXT?	YES

Prescription:

BAG VOL:	100 ml
VOL TBI:	50.0 ml
RATE:	9.9 ml/hr
TIME:	5:03 HH:MM
KVO Rate:	0.0 ml/hr
DONE?	YES

Options

AIR Sens:	0.1 ml
DN Occlu:	LOW

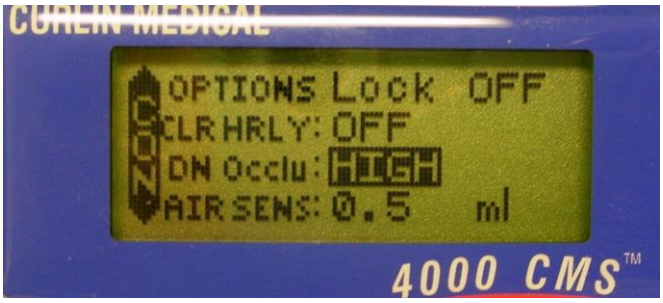
iii. Start the continuous therapy running by pressing "RUN/Pause" key.

iv. While the pump is running, occlude the output by closing the 3-way valve toward the syringe or the atmosphere.

v. Observe pressure buildup on the pressure gage. Pump will go into ALARM DOWN OCCLUSION when pressure reaches 8 PSI. Valid pressure range for low occlusion is 6.0 ≤ occlusion pressure ≤ 10.0 PSI. ***(Note: Pumps failing this criteria may be tested a second time. If pump fails a second time it must be serviced by a trained service technician.)***

vi. Release the pressure by opening the 3-way valve and observe pump automatically restarts infusion when pressure is released. Record results on the Traveler.

vii. Press PAUSE to stop the infusion and then press REPEAT Rx. Change the down occlusion threshold to High (18 PSI) using the "Option" menu.



viii. Set up the pump as shown on page 49 (the same setup as the 8-psi test), then press RUN to start the infusion.

ix. While the pump is running, occlude the output by closing the 3-way valve for the return to the beaker.

x. Observe pressure buildup on the pressure gage. Pump will go into ALARM DOWN OCCLUSION when pressure reaches 18 PSI. Valid pressure range for low occlusion is 16.0 ≤ down occlusion pressure ≤ 20.0 PSI. ***(Note: Pumps failing this criteria may be tested a second time. If pump fails a second time it must be serviced by a trained technician.)***

xi. Release the pressure by opening the valve and observe pump automatically restarts infusion when pressure is released. Record results on the Traveler, then press PAUSE to stop the infusion.

d. Test Input Strain Beam for -6 PSI Thresholds:

i. Connect the Digital Pressure Gage and a 3-way valve to the upstream side of the Moog Test Admin Set such that the pressure gage can read the up occlusion pressure.

ii. Press RESUME on the previous continuous therapy, then press RUN to start the infusion.

iii. While the pump is running, occlude the input by closing the valve towards the reservoir.

iv. Observe that the inlet pressure falls and pump will go into ALARM UP OCCLUSION when pressure reaches -6 PSI (-12.2 inHg). Valid pressure range is -8 ≤ up occlusion pressure ≤ -4 PSI (-16.3 ≤ up occlusion pressure ≤ -8.1 inHg). ***(Note: Pumps failing this criteria may be tested a second time. If pump fails a second time it must be serviced by a trained technician.)***

v. Release the pressure occlusion and observe pump will NOT restart infusion automatically. Press the Run/Pause key to clear the Up Occlusion alarm.

vi. Record the results on the Traveler.

If the pump does not meet the criteria on downstream and upstream occlusion tests:

1 Did you use a new set? If not, use a brand new one.
2 Did you prime the set? If not, prime the set until there is no air bubble inside the test set.
3 Did you turn off/on the pump after the 40-psi test? If not, turn the pump off then on.
4 Did you set up the test so that the pressure gauge measures the downstream/upstream pressure during the down/up occlusion test? If not, refer to the figures on p.49 and 51 for the respective test setups.
5 Did you record the pressure reading on the gauge as soon as you heard the occlusion alarm? If not, redo the test and record pressure readings on the gauge as soon as the occlusion alarm sounds. Since digital pressure gauges are very sensitive, we should record the pressure on the gauge as soon as we hear the occlusion alarm.

If you answered yes for the above questions and the pump still fails to meet specifications, then the pump must be serviced by a trained service technician.

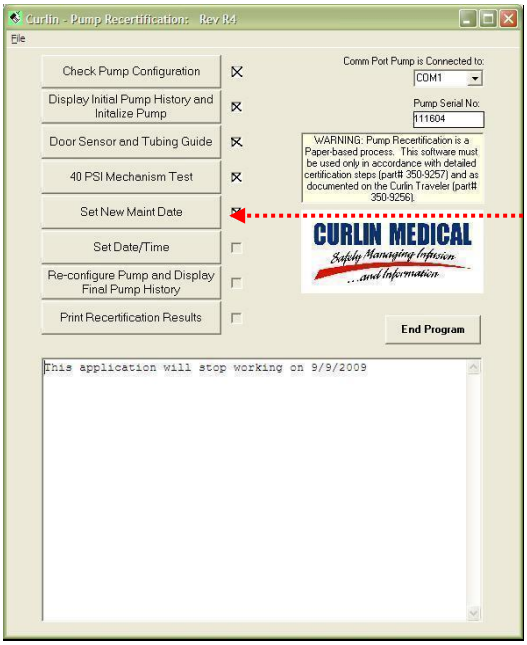
Chapter 6: Reconfiguring the Pump

After the pump finishes with the Pressure Sensors tests, the pump is now ready to be reconfigured to complete the NFR procedure. Reconnect the pump to the NFR software to begin pump reconfiguration. The steps vary somewhat if you are using the Rev R5 (PRU) or the v2 (45914). Follow the steps for the correct version of NFR software that you are using.

Rev R5 (PRU or 350-7021)

Set new Maintenance Date

Turn the pump on and allow it to finish booting (displays the PROGRAM / BIOMED SETUP screen.) From the PRU, select "Set New Maint Date". After the pump has been programmed with the new maintenance date, turn the pump OFF and back ON. Select BIOMED SETUP and enter the Clinician code 94629. Observe that the maintenance date is set one year from today's date.

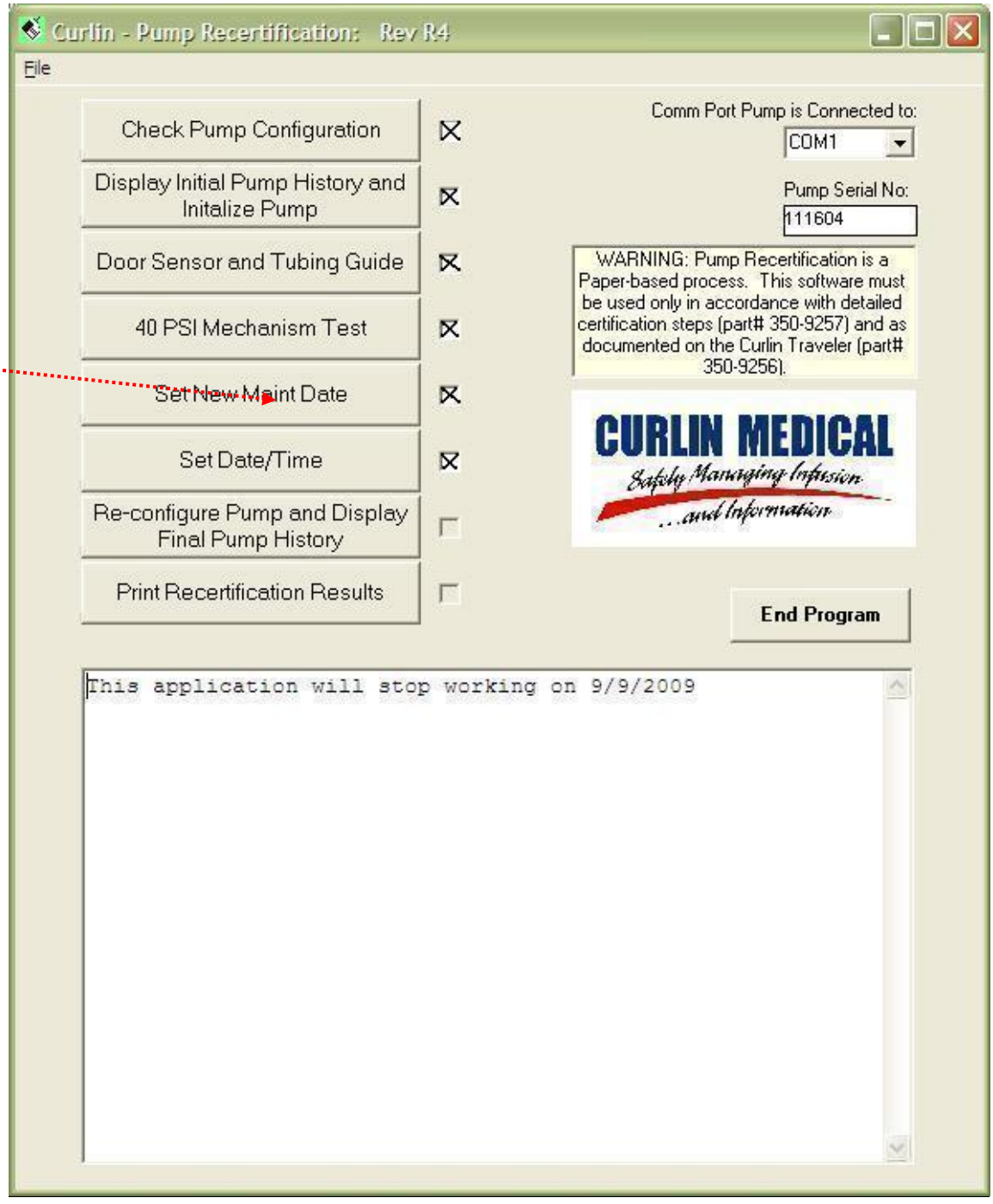

Curlin - Pump Recertification: Rev R4
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
111604
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 9/9/2009

Note: If maintenance date does not reset to correct date, and or the manufacture date resets. Perform the following functions:

With the PC Serial Port connected to Bolus/Data connector of the pump to be serviced. Press the "Door Sensor and Tubing Guide" button on the NFR software (Moog P/N 350-7021.) Enter the new maintenance date, press enter, and then press enter to accept. Scroll up one to the manufacture date press enter and observe if it is the correct date based on the original pump history displayed. If incorrect change to the date listed on the pump history and press enter, and then press enter to accept. Scroll to the bottom and press Yes/Enter to return to the menu.

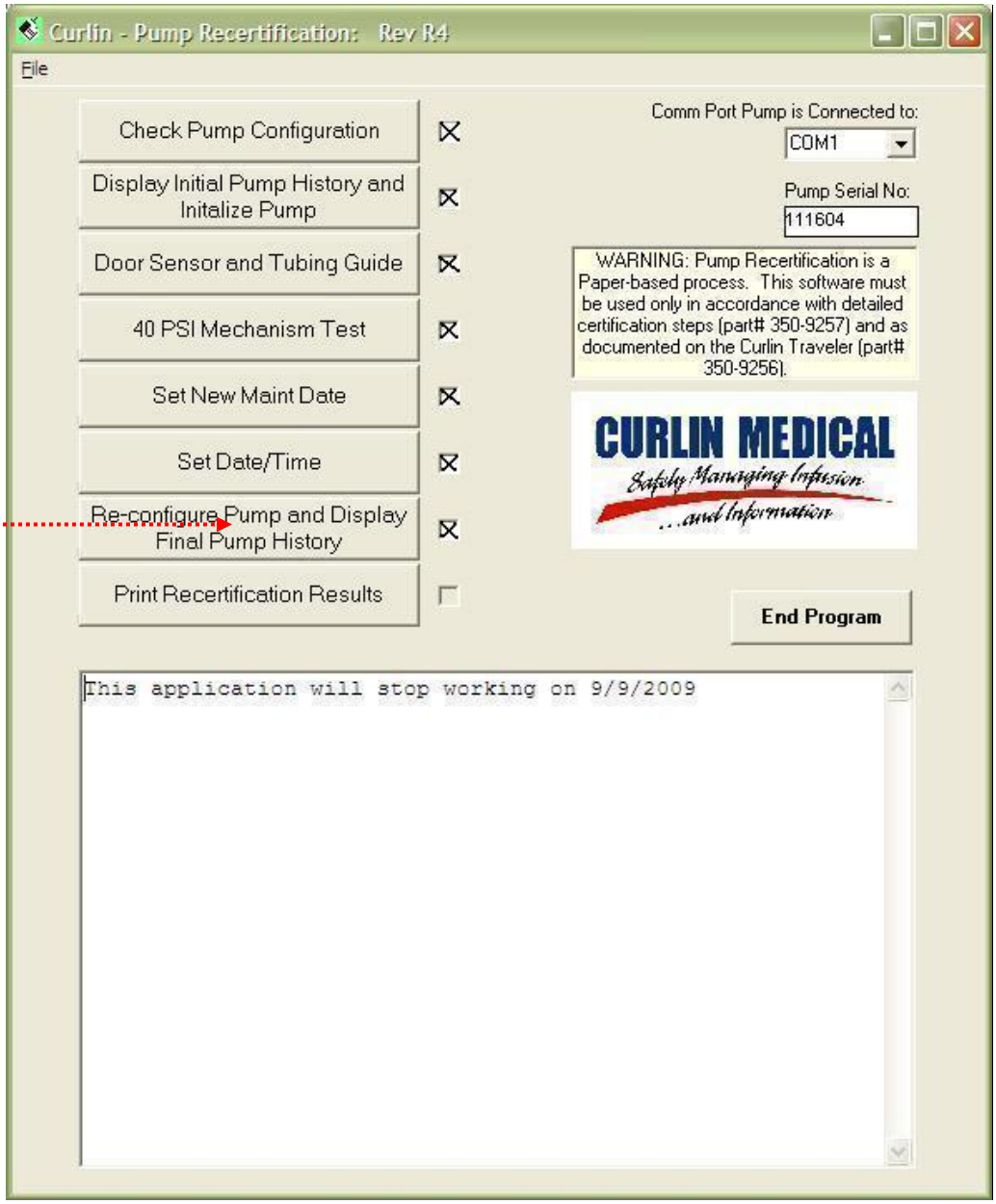
Set Date and Time

From the PRU, select "Set Date/Time". After the date and time have been set, turn the pump off and on and observe the startup screen indicate the correct date and time.


Curlin - Pump Recertification: Rev R4
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
111604
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 9/9/2009

Reconfigure Pump and Display Final Pump History

From the PRU, select "Re-configure Pump and Display Final Pump History". Observe the Pump Hx being downloaded from the pump. Clear the alarm on the pump as instructed by the PRU.


Curlin - Pump Recertification: Rev R4
File
Check Pump Configuration
Display Initial Pump History and Initalize Pump
Door Sensor and Tubing Guide
40 PSI Mechanism Test
Set New Maint Date
Set Date/Time
Re-configure Pump and Display Final Pump History
Print Recertification Results
Comm Port Pump is Connected to:
COM1
Pump Serial No:
111604
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9257) and as documented on the Curlin Traveler (part# 350-9256).
CURLIN MEDICAL
Safely Managing Infusion ...and Information
End Program
This application will stop working on 9/9/2009

Note: If the pump was an E-Config pump, the PRU will set the E-Config back to what it was before (including Lock Level, Max Basal Rate / Bolus Dose, and IOD).

Print Recertification Results

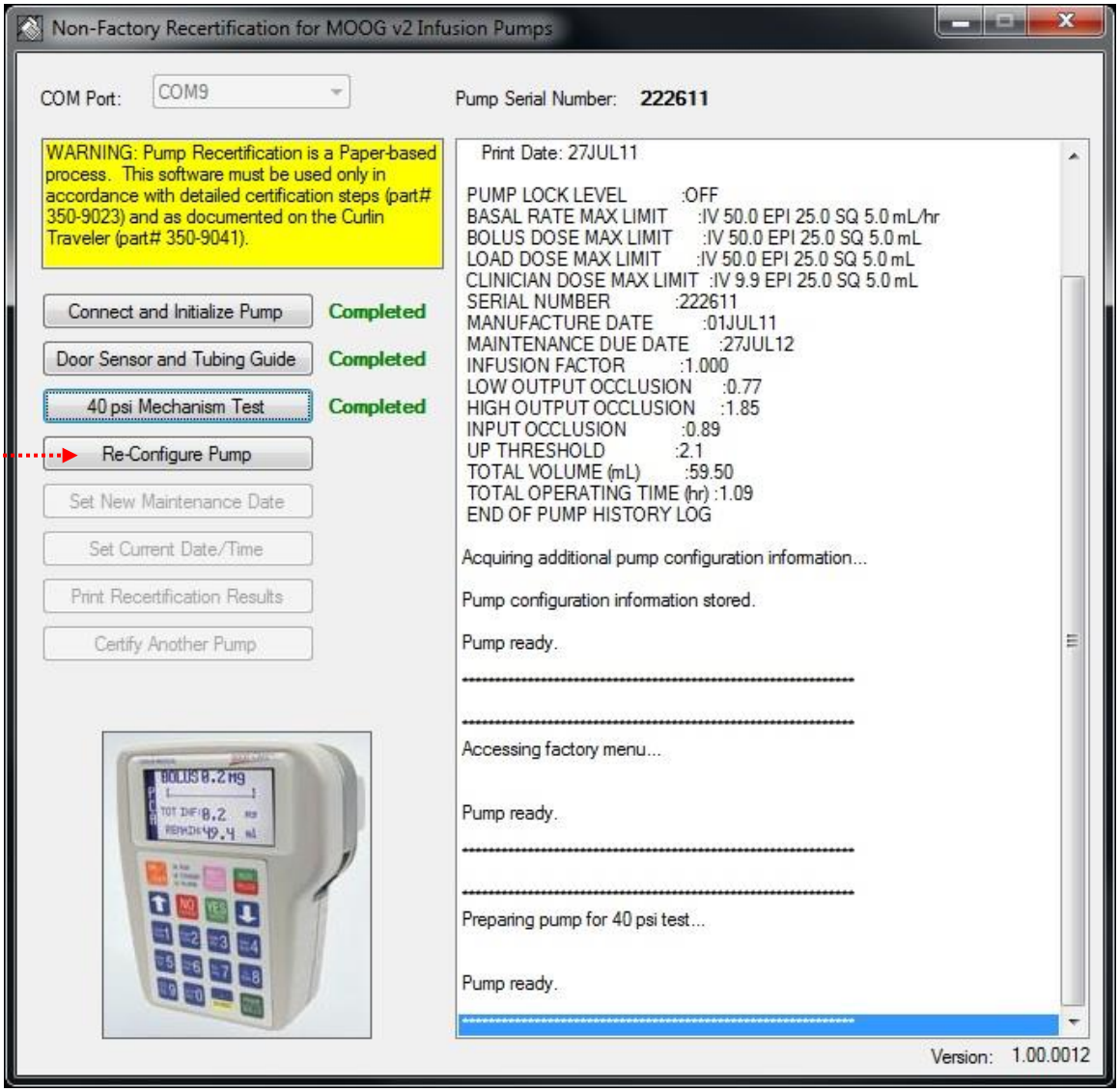
Finish the pump testing by selecting the "Print recertification Results" button on the PRU on the same PC which the recertification process begins with. Continue the print process by selecting the appropriate printer and pressing the Print button. You must see the words "pump recertification completed at" followed by the date and time. If the above is not visible, you are not done. Repeat this step. If the problem persists, return the pump to Moog.

Make sure to use the same PC that you start the Recertification process with. If the PC crashes during re-certification, reboot the PC and restart the recertification on the same PC. If the PRU reports a mismatch between the calibration data in the pump, or the pump ends up in an unexpected configuration, the pump must be returned to Moog or its affiliate for re-calibration and reconfiguration.

V2: (AS 45914)

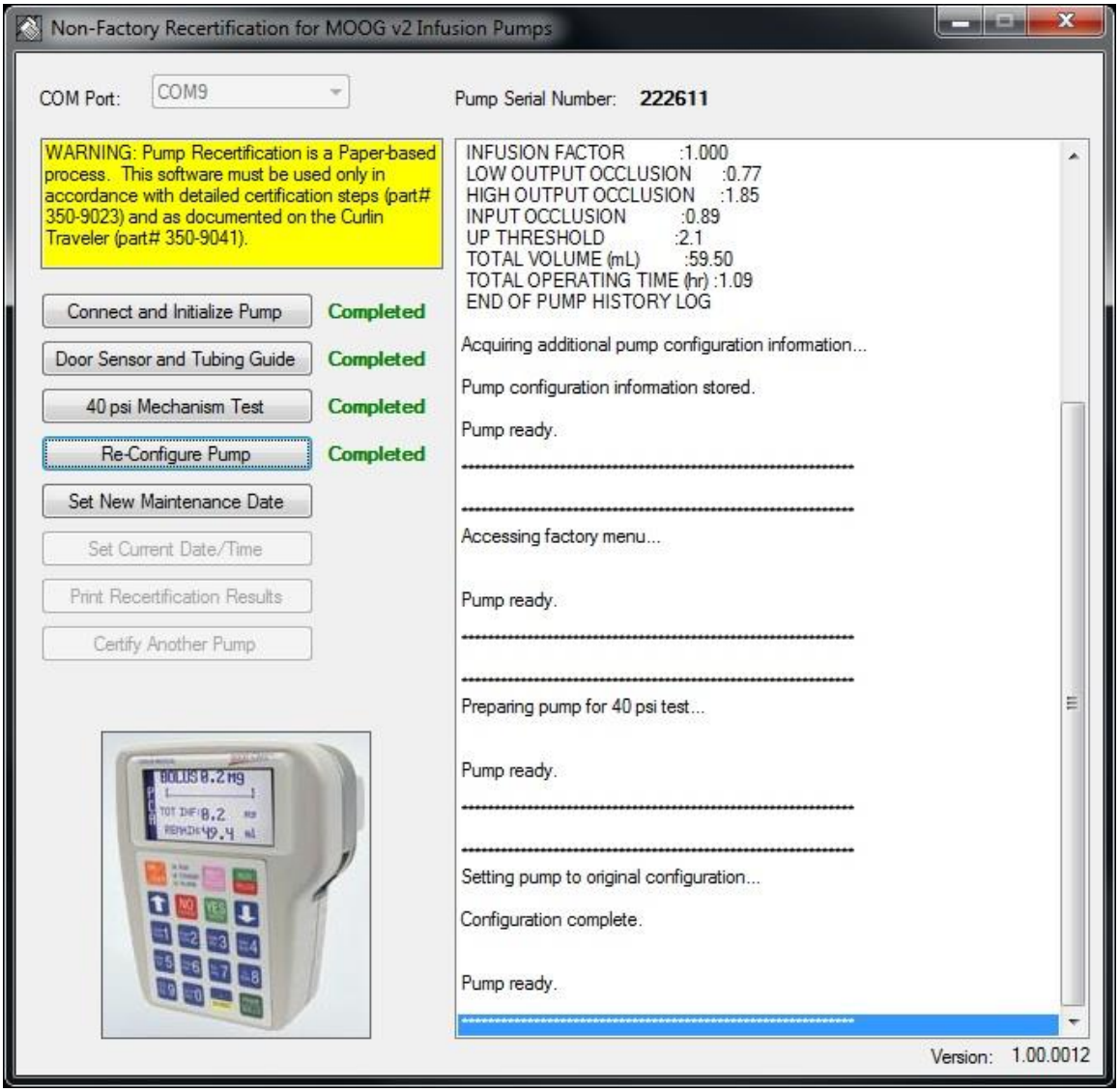
Reconfigure Pump and Display Final Pump History

From the NFR, select "Re-configure Pump". Observe the Pump Hx being downloaded from the pump. Clear the alarm on the pump as instructed by the NFR.


Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port:
COM9
Pump Serial Number: 222611
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump
Completed
Door Sensor and Tubing Guide
Completed
40 psi Mechanism Test
Completed
Re-Configure Pump
Set New Maintenance Date
Set Current Date/Time
Print Recertification Results
Certify Another Pump
Print Date: 27JUL11
PUMP LOCK LEVEL :OFF
BASAL RATE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL/hr
BOLUS DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
LOAD DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
CLINICIAN DOSE MAX LIMIT :IV 9.9 EPI 25.0 SQ 5.0 mL
SERIAL NUMBER :222611
MANUFACTURE DATE :01JUL11
MAINTENANCE DUE DATE :27JUL12
INFUSION FACTOR :1.000
LOW OUTPUT OCCLUSION :0.77
HIGH OUTPUT OCCLUSION :1.85
INPUT OCCLUSION :0.89
UP THRESHOLD :2.1
TOTAL VOLUME (mL) :59.50
TOTAL OPERATING TIME (hr) :1.09
END OF PUMP HISTORY LOG
Acquiring additional pump configuration information...
Pump configuration information stored.
Pump ready.
Accessing factory menu...
Pump ready.
Preparing pump for 40 psi test...
Pump ready.
Version: 1.00.0012

When the pump finishes the reconfiguration process, it should be in the same configuration that it had when the NFR procedure was started. Review the pump history as seen on the screen to see if any new Malfunction or Error Codes are displayed. Check the manufacture date of the pump as shown on the pump history to make sure it did not change.

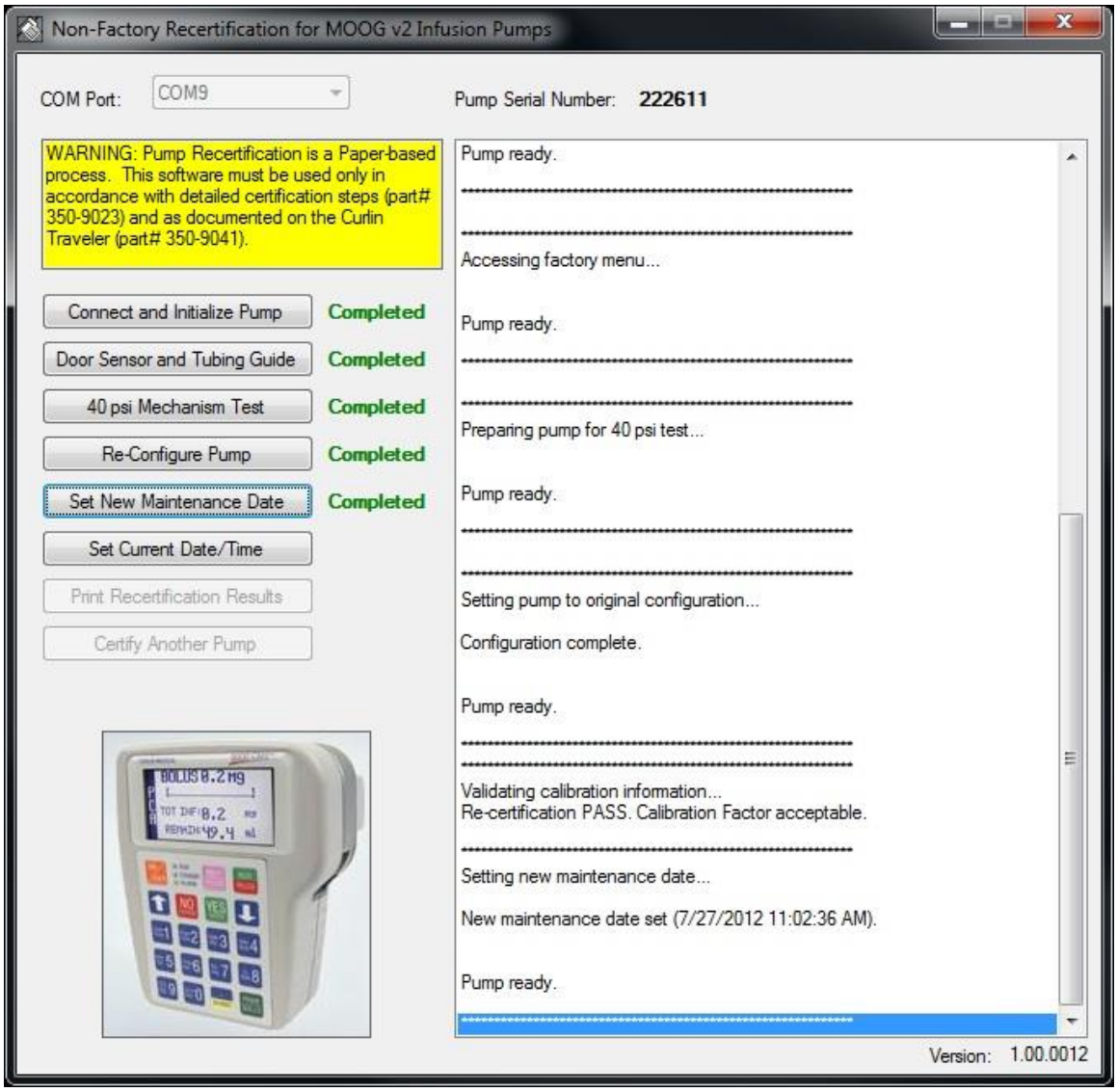
Set new Maintenance Date



From the NFR, select "Set New Maint Date". After the pump has been programmed with the new maintenance date, turn the pump OFF and back ON. Select BIOMED SETUP and enter the Clinician code 94629. Observe that the maintenance date displayed there is the same as the date on the NFR screen, set one year from today's date. Scroll to the bottom and select Yes/Enter.

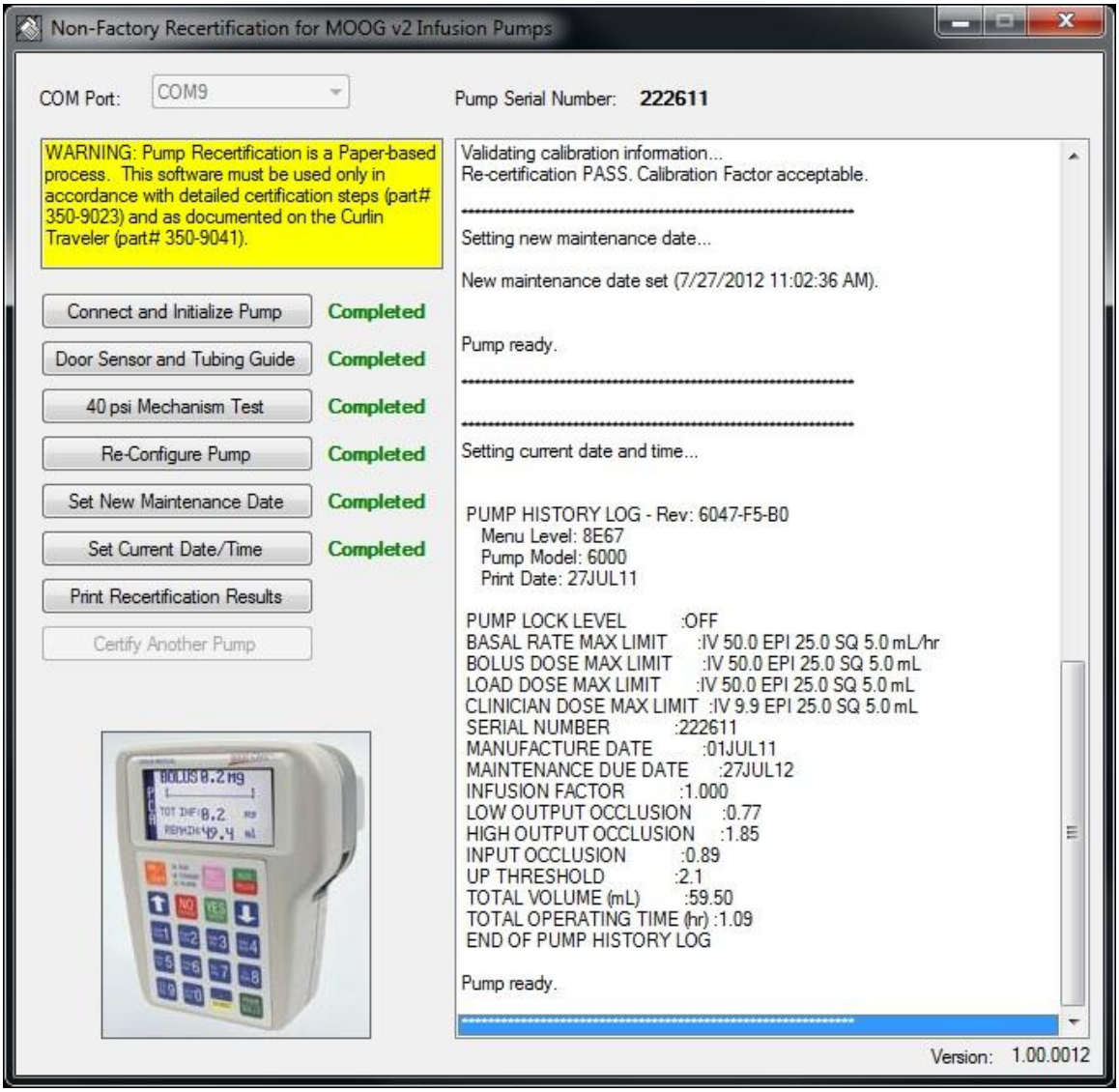
Set Current Date and Time

Select "Set Current Date/Time" and wait until it shows "Completed" beside the button.



Print Recertification Results

Finish the pump testing by selecting the "Print recertification Results" button on the NFR on the same PC which the recertification process begins with. Continue the print process by selecting the appropriate printer and pressing the Print button. You must see the words "pump recertification completed at" followed by the date and time. If the above is not visible, you are not done. Repeat this step. If the problem persists, return the pump to Moog.


Non-Factory Recertification for MOOG v2 Infusion Pumps
COM Port: COM9
Pump Serial Number: 222611
WARNING: Pump Recertification is a Paper-based process. This software must be used only in accordance with detailed certification steps (part# 350-9023) and as documented on the Curlin Traveler (part# 350-9041).
Connect and Initialize Pump Completed
Door Sensor and Tubing Guide Completed
40 psi Mechanism Test Completed
Re-Configure Pump Completed
Set New Maintenance Date Completed
Set Current Date/Time Completed
Print Recertification Results
Certify Another Pump
Validating calibration information...
Re-certification PASS. Calibration Factor acceptable.
Setting new maintenance date...
New maintenance date set (7/27/2012 11:02:36 AM).
Pump ready.
Setting current date and time...
PUMP HISTORY LOG - Rev: 6047-F5-B0
Menu Level: 8E67
Pump Model: 6000
Print Date: 27JUL11
PUMP LOCK LEVEL :OFF
BASAL RATE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL/hr
BOLUS DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
LOAD DOSE MAX LIMIT :IV 50.0 EPI 25.0 SQ 5.0 mL
CLINICIAN DOSE MAX LIMIT :IV 9.9 EPI 25.0 SQ 5.0 mL
SERIAL NUMBER :222611
MANUFACTURE DATE :01JUL11
MAINTENANCE DUE DATE :27JUL12
INFUSION FACTOR :1.000
LOW OUTPUT OCCLUSION :0.77
HIGH OUTPUT OCCLUSION :1.85
INPUT OCCLUSION :0.89
UP THRESHOLD :2.1
TOTAL VOLUME (mL) :59.50
TOTAL OPERATING TIME (hr) :1.09
END OF PUMP HISTORY LOG
Pump ready.
Version: 1.00.0012

Make sure to use the same PC that you start the Recertification process with. If the PC crashes during re-certification, reboot the PC and restart the recertification on the same PC. If the NFR reports a mismatch between the calibration data in the pump, or the pump ends up in an unexpected configuration, the pump must be returned to Moog or its affiliate for re-calibration.

Chapter 7: Replacing Components & Subassemblies

REQUIRED EQUIPMENT

The following equipments are required to service the pump:

- Hex Key Set (.050", 1/16", 5/64")
- Socket Nut Driver Set (5/32", 3/16")
- Lemo Plier (Moog P/N: 360-5013)
- Lemo Tool (Moog P/N: 340-5048)
- Torque Wrenches 2#, 3#, and 4#
- Soldering Iron (Weller EC1002 or equivalent)
- LOCTITE 222 (Moog P/N: C60-04018)
- Torque Seal F-900 (Moog P/N: C60-04010)
- RTV (Moog P/N: C60-04000)
- EMI Gasket Seal Cord (Moog P/N: C55-11001)
- Isopropyl Alcohol
- Compress Air (clean and oil free)
- Non-Factory Recertification Software, NFR (Moog P/N: 350-7021/AS-45914).
- Non-Factory Service Traveler (Moog P/N: 350-9041)
- Data Interface Cable for PC (Moog P/N: 340-2011)
- Personal Computer with Microsoft Windows: 2000 or XP

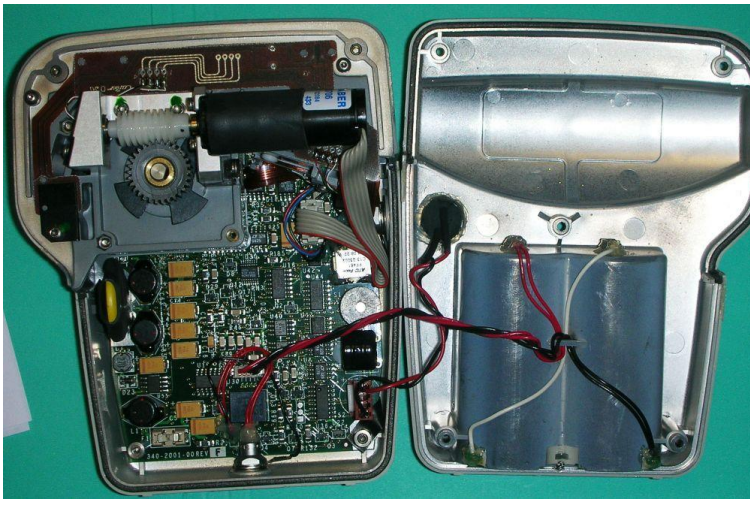
Note: Electrostatic-Sensitive Devices, observe handling precautions.

Note: IPC Certification for PCB Reword and Repair (7711B/7721B) is required to service PCB components

OPENING PUMP CASE

1 OPEN THE PUMP CASE AND REMOVE PUMP MECHANISM AS FOLLOWS:

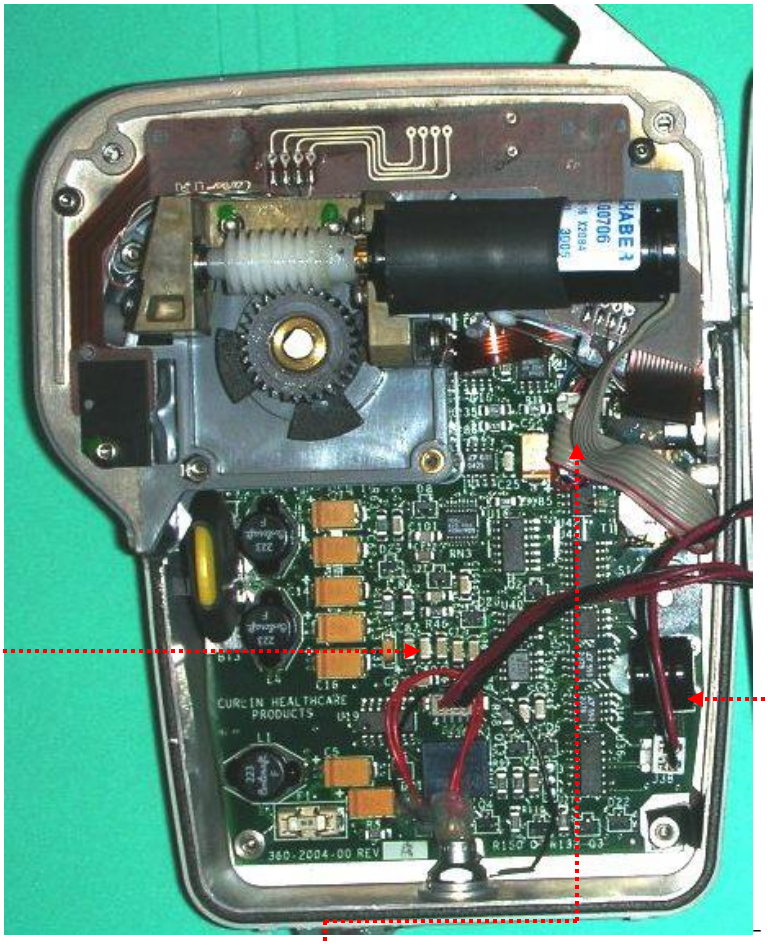
a. Using a 5/64" Hex driver, remove the five screws item 5 and 6 (Fig. 2.1) from the back side of the pump.



4000

6000 / PainSmart

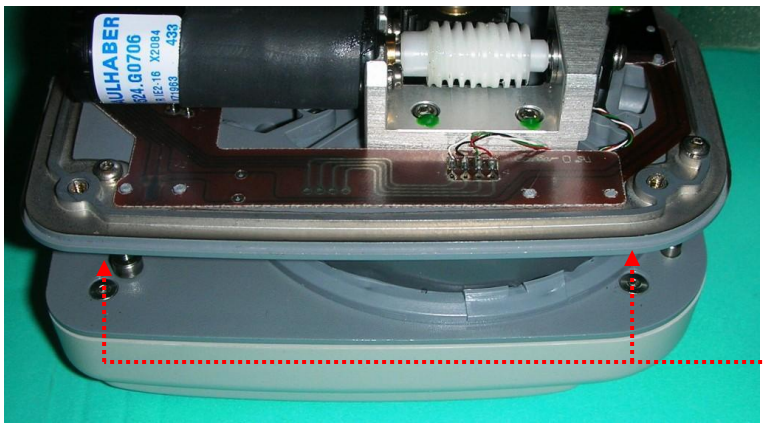
b. Carefully lift the Rear Case item 3 (Fig. 2.1) to separate from the rest of the pump. Disconnect the Battery Cable Connector, and the Main Speaker Cable Connector item 12 (Fig. 2.1) from the PCB, then remove the Rear Case.

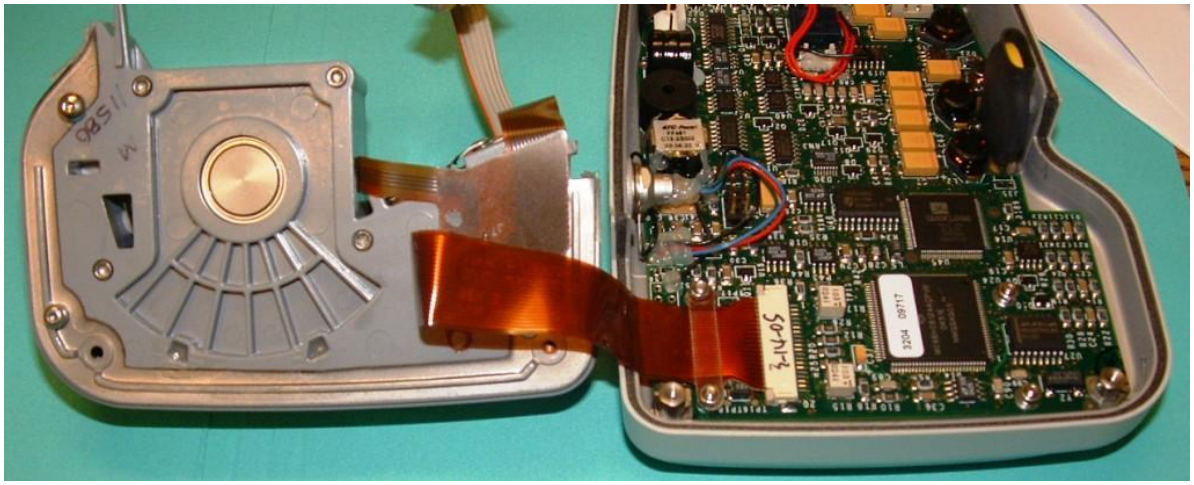


c. Disconnect the Motor Connector item 9 (Fig. 2.1) from the PCB.

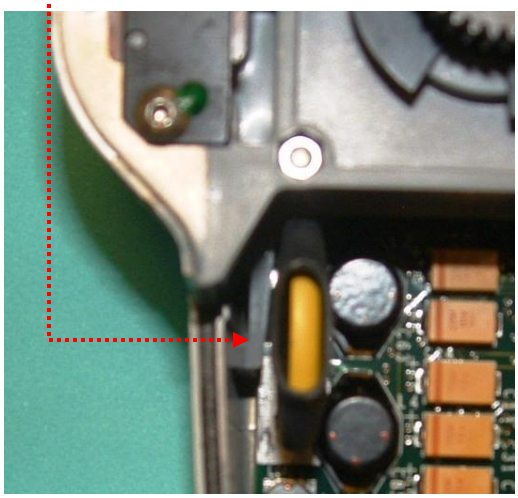
2 Remove Motor Assembly

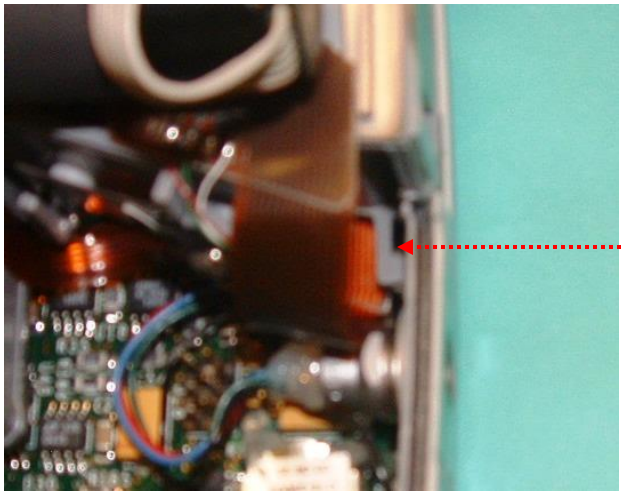
a. Open the Pump Door then using a .050" Hex driver, remove the two Flat Head Hex screw item 4 (Fig. 2.1) from the Pump Mechanism.

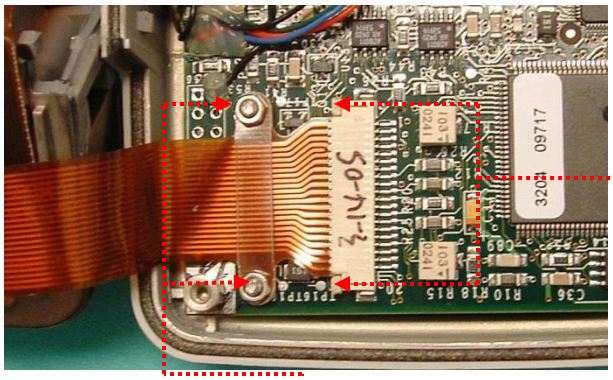




b. Carefully lift the top of the Mechanism away from the Front Case, and slide it towards the top of the pump to disengage the latching tabs on the mechanism from the Front Case. (Caution: the Flex Circuit Connector is still attached to the PCB).







c. Using a 5/32" nut driver, remove the two nuts that are holding the Flex Circuit Cable to the PCB(**2000 and 4000 only**), then unlatch the J32 connector and disconnect the Flex Circuit Cable connector. The mechanism should be free to be separated from the pump.

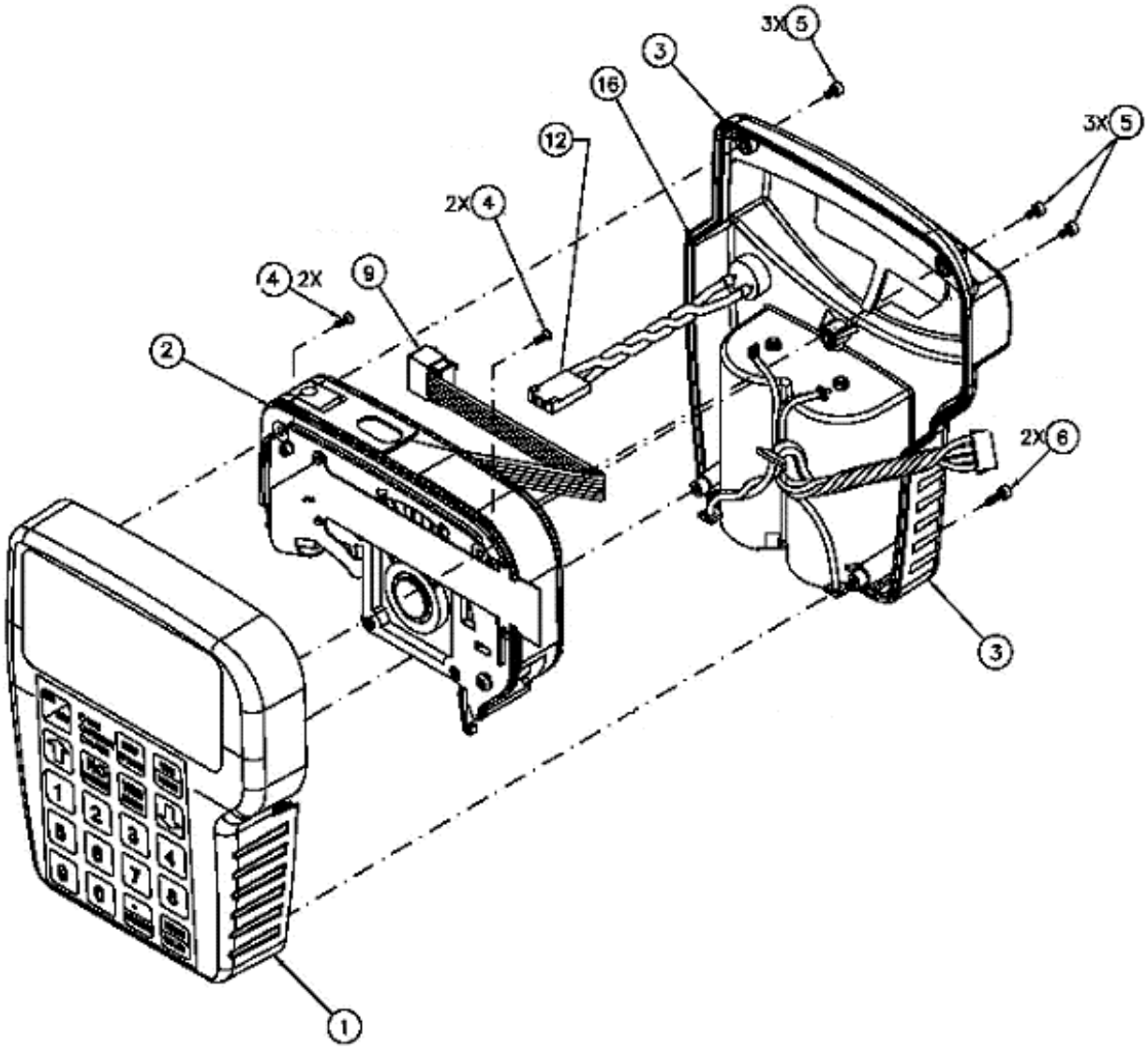


Figure 2.1 Pump Assembly

3 **INSTALL PUMP MECHANISM**

a. Connect the FLEX CIRCUIT CONNECTOR of the PUMP MECHANISM to the J32 connector of the PCB. Secure it with two #2 nuts and torque nuts to 2 lb-in, then secure the latch of J32 connector

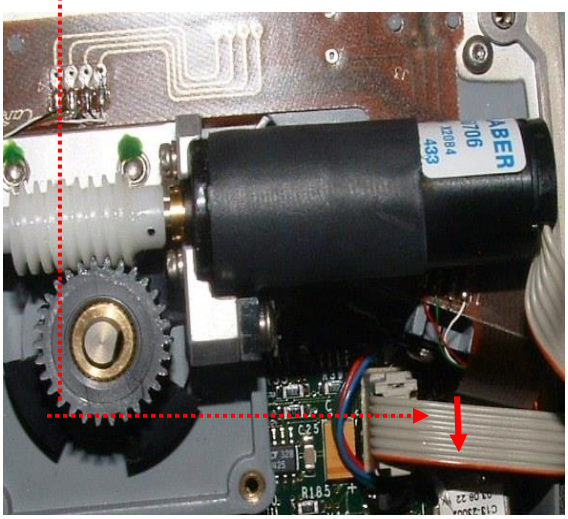
b. Secure the PUMP MECHANISM to the FRONT CASE by sliding it in position such that the latching tabs on the Pump Mechanism are engaged with the matching features on the Front Case. Fasten the Pump Mechanism to the Front Case with the two fasteners item 4 (Fig. 2.1) and torque to 2 lb-in.

c. Connect the BATTERY CABLE connector of the REAR CASE to the J30 connector of the PCB..

d. Connect the MAIN SPEAKER CABLE connector to the J36 connector of the PCB. Item 12 (Ref. Fig. 2.1).

e. Connect the Motor Cable connector item 9 (Fig. 2.1) to J28 of the PCB.

Note: Ensure that the red strip on the cable is facing the external power LEMO connector.



f. PERFORM PRESSURE SENSOR BASELINE CALIBRATION following the procedure described in Chapter 8(Pg. 85).

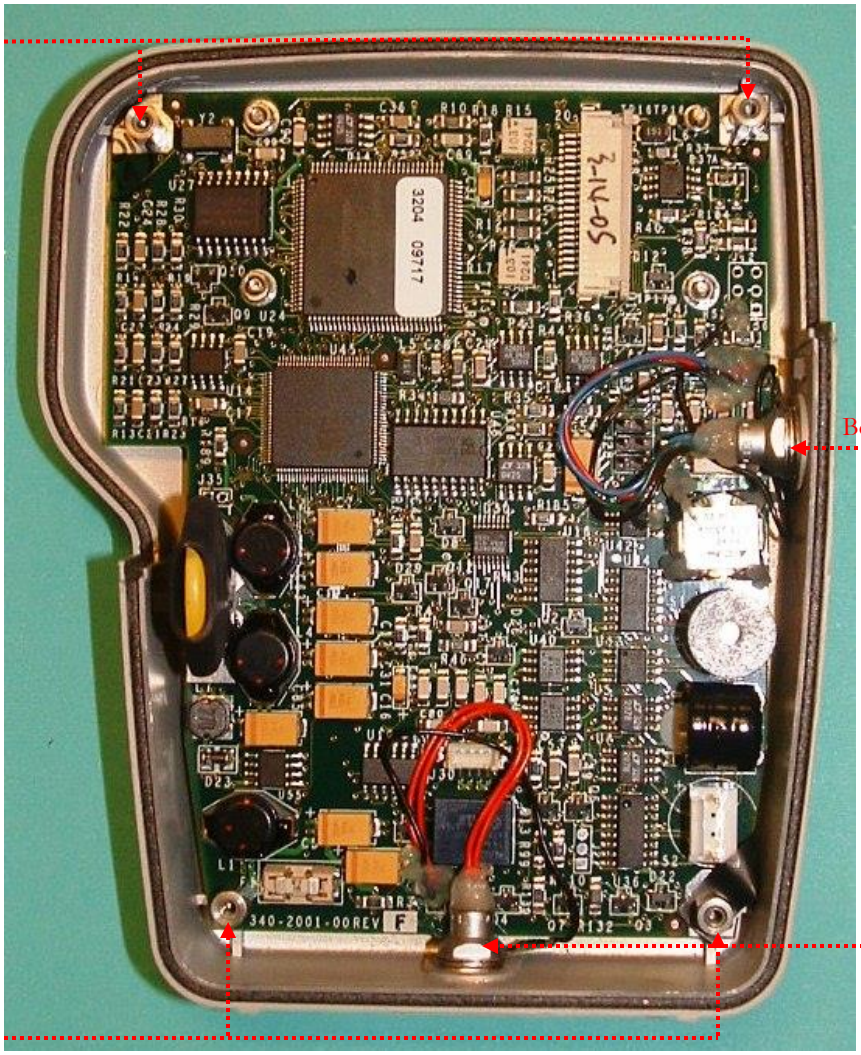
Replacement of Electronic PCB

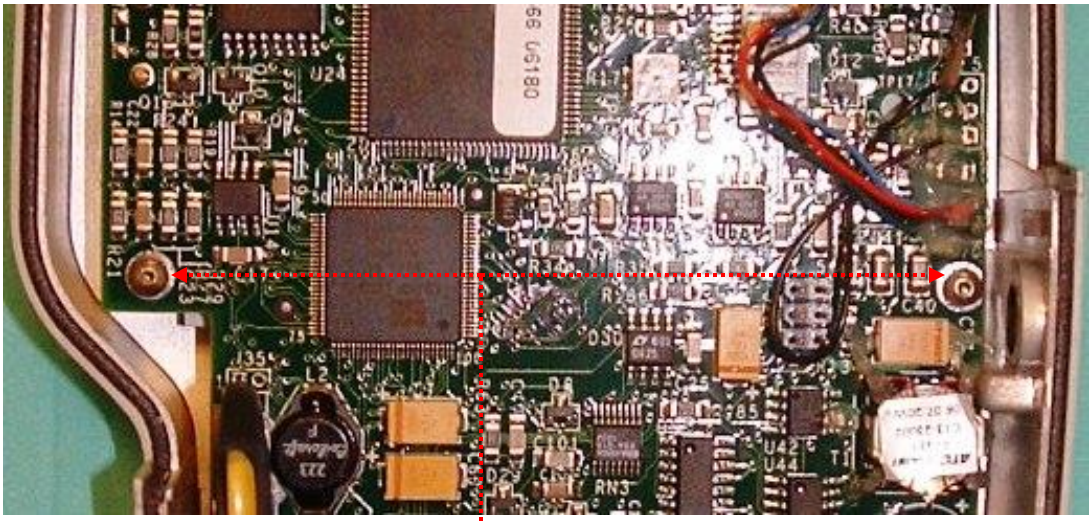
1 OPEN PUMP AND REMOVE THE PUMP MECHANISM following the instructions described in the section "**Opening Pump Case**" (Pg. 61).

2 **REMOVE PCB**

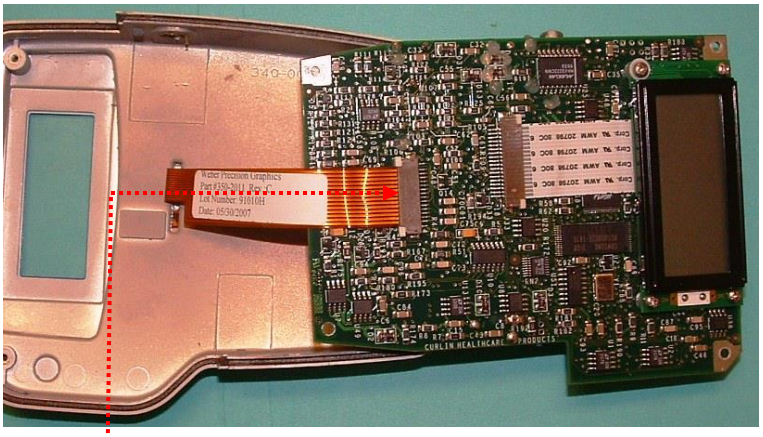
a. Remove the two LEMO connectors (Power & Bolus) item 4 (Fig. 2.3). Use tool P/N: 360-5013 to hold LEMO connector from the inside of the Front Case, loosen and remove the LEMO nut item 6 (Fig. 2.3) with tool P/N: 340-5048, then remove washers item 5 (Fig. 2.3) and pull the LEMO connector out of position from the inside of the Front Case *(Note: handle the connectors with care to prevent damage to the connecting wires).*

b. Remove four M/F Hex Standoffs item 1 (Fig. 2.3), then lift the PCB item 3 (Fig. 2.3) gently and turn the PCB to expose the Keypad Connector on the other side of the PCB. (**2000 and 4000 only**)

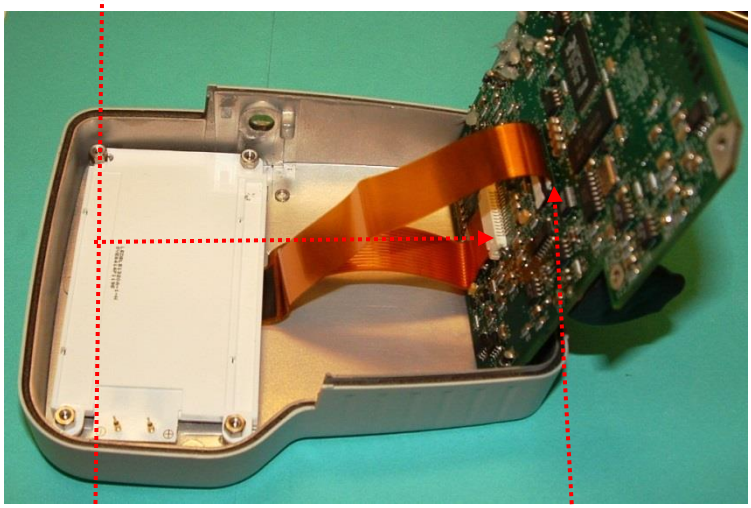




c. The 6000 has 2 additional screws that must be removed using the 0.50" hex driver.



4000

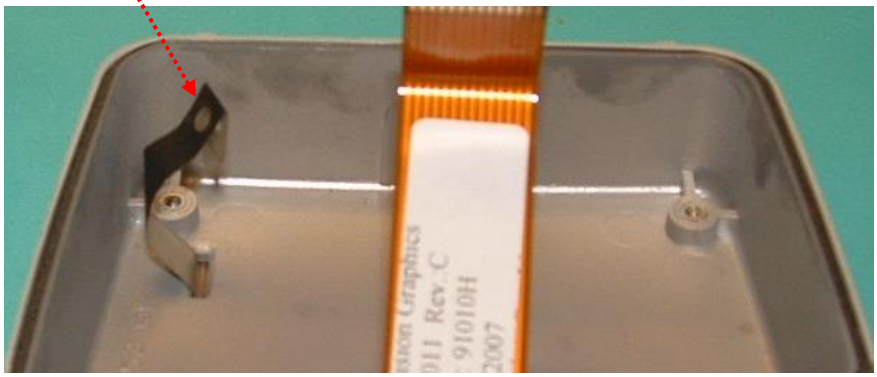


6000

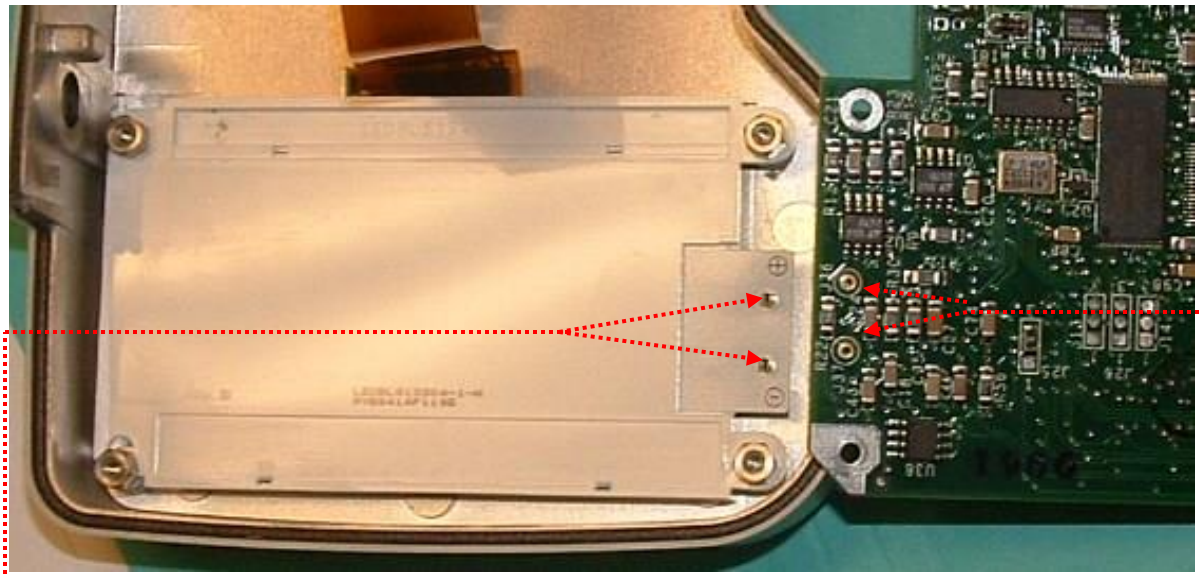
d. Disconnect the Keypad Cable and also the LCD cable on the 6000.

3 INSTALL THE PCB

a. Fold ESD tab item 8 (Fig. 2.3) of keypad in half so that the 2 holes are aligned.



b. Attach the Keypad Cable connector to J31 on the PCB (Fig. 2.6) and latch the connector securely.



c. Place the PCB in the front housing. For the 6000 pump be careful to line up the LCD connector with the PCB plugs.

d. Mount the PCB ASSY to the FRONT CASE and fasten with two M/F HEX STANDOFF (SHORT) item 1 (Fig. 2.3) through the two holes closer to the LCD opening on the upper side of the FRONT CASE. Torque standoffs to 3 in-lb.

e. Secure the PCB ASSY and the grounding strap of the KEYPAD ASSY to the FRONT CASE by two M/F Hex Standoffs (LONG) through the two holes on the lower side of the FRONT CASE. Torque standoffs to 3 in-lb.

f. Clean then re-apply a small amount of RTV around the two recessed areas of the FRONT CASE where the LEMO connectors are going to be installed.

g. With the KEYPAD ASSY facing down and the bottom opening facing you, line up the EXT. PWR. LEMO connector so that the red dot is on the right hand side.

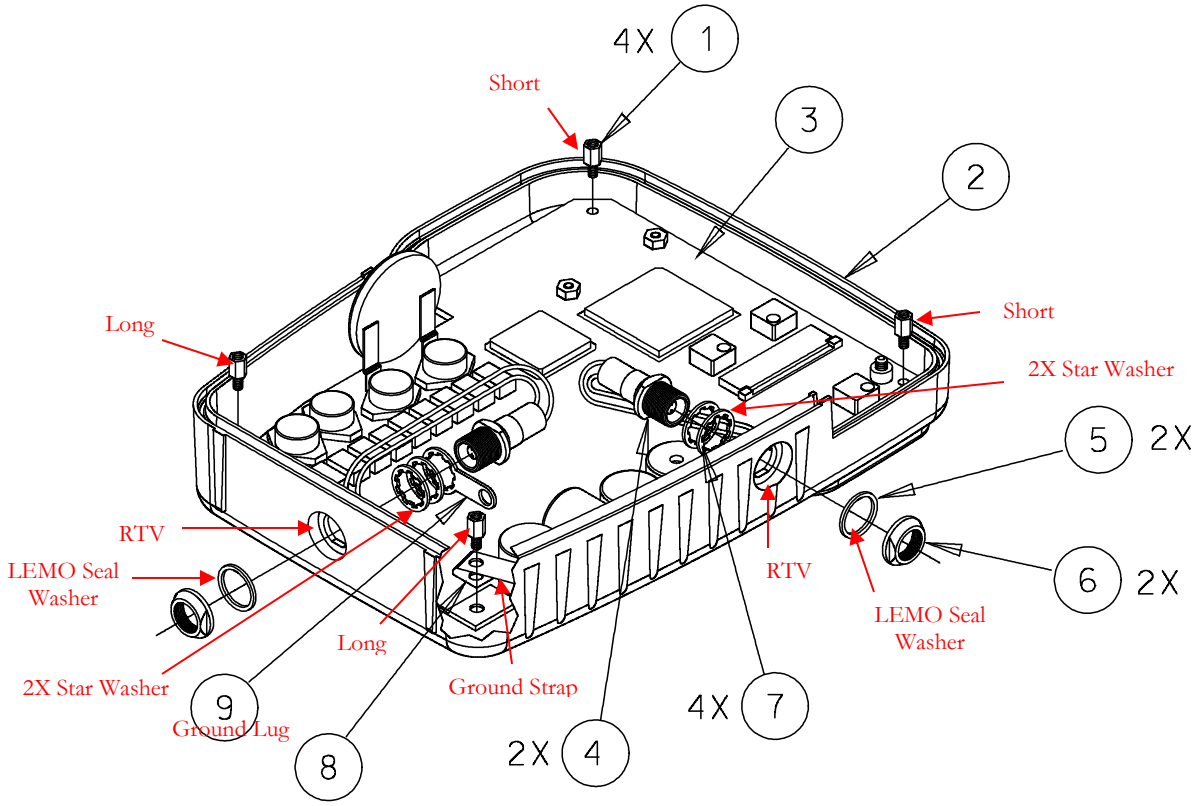


Figure 2.3 Front Case Assembly 4000

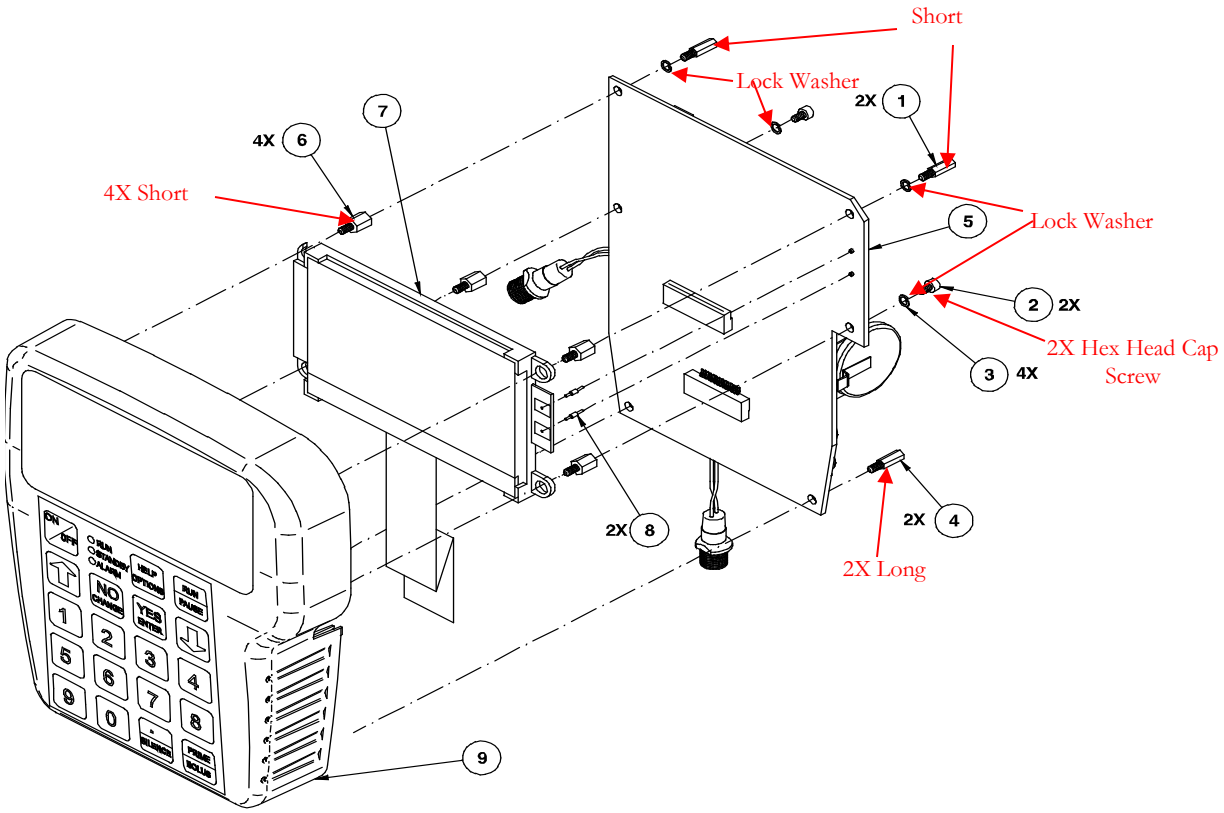


Figure 2.4 Front Case Assembly 6000

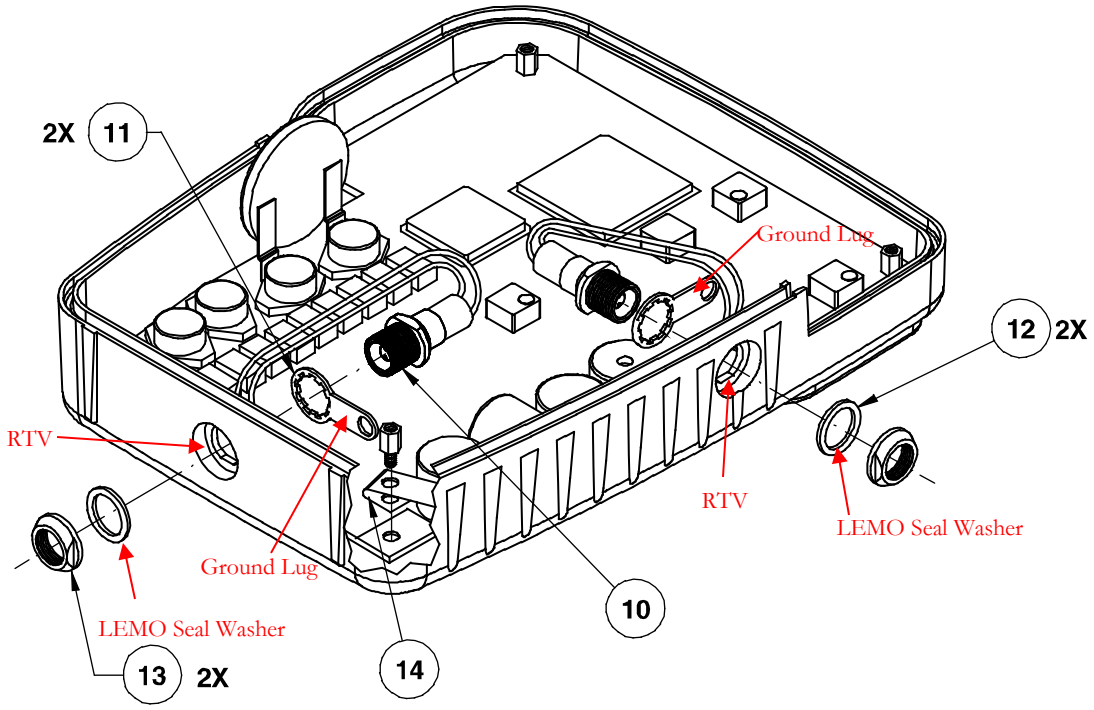


Figure 2.5 LEMO ASSEMBLY 6000

h. With both star washers item 7 (Fig. 2.3) of the EXT. PWR. LEMO connector and the GROUND LUG item 9 (Fig. 2.3) on the inside and one LEMO SEAL WASHER item 5 (Fig. 2.3) on the outside of the pump case, secure the connector to the FRONT CASE. Apply a small amount of LOCTITE 222 to the threads of the connector. Use tool 360-5013 to hold LEMO connector while tightening nut item 6 (Fig. 2.3) with tool 340-5048. Torque the nut to 4 in-lb.

i. With the KEYPAD ASSY facing down and the side opening facing you, line up the DATA/BOLUS LEMO connector so that the red dot is on the right hand side, lined up with the arrow on the front case.

j. With both star washers item 7 (Fig. 2.3) of the DATA/BOLUS LEMO connector on the inside and one LEMO SEAL WASHER item 6 (Fig. 2.3) on the outside of the pump case, secure the connector to the FRONT CASE. Apply a small amount of LOCTITE 222 to the threads of the connector. Use tool 340-5042 to hold LEMO connector while tightening nut with tool 340-5010. Torque the nut to 4 in-lb.

4 6000 SERIES PCB REPLACEMENT

a. A couple of differences are seen with the front housing assembly of a 6000 series pump.

b. The LCD for a 6000 series pump is mounted to the front housing and not the PCB. Use 4 short standoffs as shown in Figure 2.4 to secure the LCD to the front housing.

c. When placing the PCB in the front housing, ensure the pins of the LCD seat properly in the receptacles of the PCB. You will know this when the PCB sits flat all the way down in the housing.

d. The short standoffs used to secure the top of the PCB should each have a lock washer as shown in figure 2.4.

e. The PCB is also secured to the LCD by 2 Hex head cap screws. These screws should also have lock washers.

f. The LEMO connectors do not use star washers on the 6000 series pump. See Figure 2.5.

g. All other steps are identical to the 4000 series pump.

5 INSTALL THE PUMP MECHANISM following the instructions described in the section "**Install Pump Mechanism**" (Pg. 65).

6 CLOSE THE PUMP CASE following the instructions described in the section "**Close the Pump**" (Pg. 81).

7 PERFORM 48 HOURS BURN-IN TEST AS FOLLOWS:

a. Install a primed Administration Set into the pump (Moog P/N 340-4123-02) with ends connected to a water reservoir.

b. Connect pump to AC Adapter.

c. Turn On pump and program the pump for a Variable Therapy according to Fig. 2.8.

Field	Data	Dose 1	Dose 2	Dose 3	Dose 4	Dose 5	Dose 6	Dose 7	Dose 8	Dose 9	Dose 10	Dose 11	Dose 12	Units
UNITS	Ml													
DELAY	Off													
BAG Vol	9999													ml
#DOSES	12													
KVORATE	0.1													ml/hr
Amt TBI		1600	500	60	40	1600	500	60	4	1600	500	60	0.4	ml
RATE		400	125	15	10	400	125	15	1	400	125	15	0.1	ml/hr
TIME		4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	HH:MM
TOT DOSES	12													
TOT Time	48:00													HH:MM
REQ Vol	6524													ml

Figure 2.8 48 Hour Burn In Variable Therapy

d. Set Options to the following:

i. DN Occlu: LOW

ii. AIR SENS: 0.5 ml

8 Run the Therapy. Do not disable any alarms or malfunction.

9 PERFORM FUNCTIONAL TEST following the procedure in Chapter 5 (Pg. 40).

10 PERFORM VOLUME ACCURACY CALIBRATION by following the procedure described in Chapter 8 (Pg. 82).

Replacement of Front Case with Keypad

1 OPEN PUMP AND REMOVE PUMP MECHANISM following the instructions described in the section "**Opening Pump Case**" (Pg. 61).

2 REMOVE PCB following the instructions described in the section "**Replacement of Electronic PCB**" (Pg. 66).

3 Clean the new Front Case with Isopropyl alcohol.

4 Install the EMI Gasket Seal Cord (C55-11001) around the new Front Case groove.

5 RE-INSTALL THE PCB following the instruction described in the section "**Install the PCB**", (Pg. 68).

6 INSTALL THE PUMP MECHANISM following the instructions described in the section "**Install Pump Mechanism**" (Pg. 65).

7 CLOSE PUMP CASE following the instructions described in the section "**Close the Pump**" (Pg. 81).

8 PERFORM FUNCTIONAL TEST following the procedure in Chapter 5 (Pg. 40).

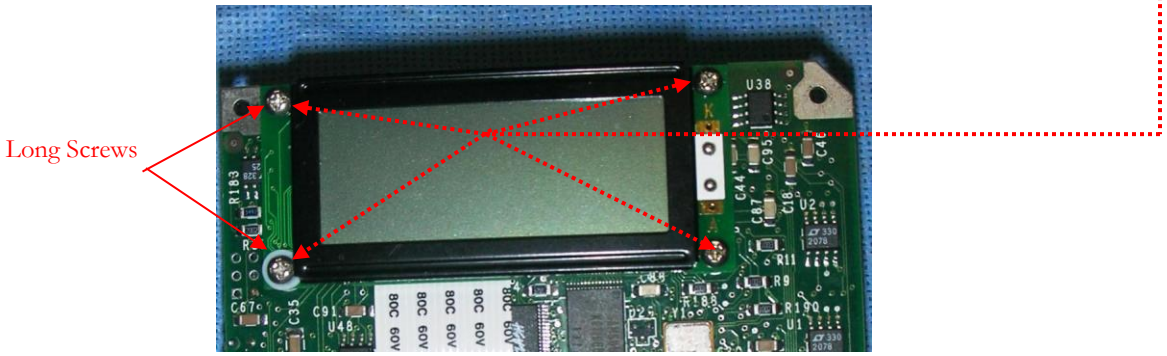
Replacement of LCD

1 OPEN PUMP AND REMOVE PUMP MECHANISM following the instructions described in the section "**Opening Pump Case**" (Pg. 43).

2 REMOVE PCB following the instructions described in the section "**Replacement of Electronic PCB**", steps 2a through 2c.

3 REPLACE THE 4000 LCD AS FOLLOWS:

a. Using a 5/32" nut driver, remove the four #2 hex nuts and two lock washers, then turn the PCB over and lift the LCD gently to expose the LCD Connector. (*Note: The two longer screws are on the left of the LCD when facing the LCD screen)*



b. Unlatch the LCD connector J33 (Fig. 2.6) and disconnect the LCD Cable connector.

c. Remove and replace the LCD.

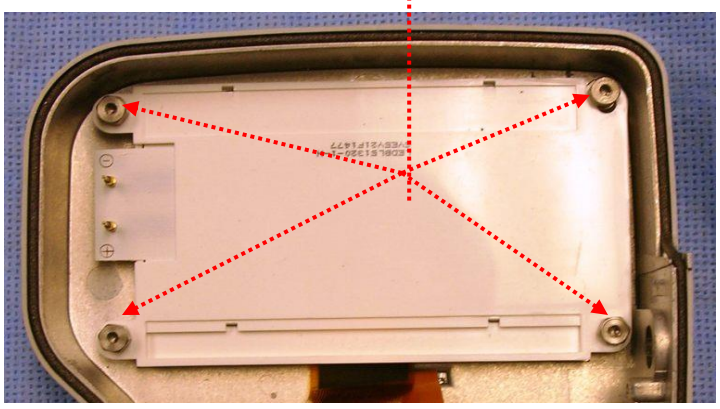
d. Install the new LCD by reversing the above steps. Torque the fasteners to 2 in-lb. (*Note: The two lock washers are for the shorter screws of the LCD)*

4. REPLACE THE 6000 LCD AS FOLLOWS:

a. Unlatch the LCD connector J33 (Fig. 3.5) and disconnect the LCD Cable connector.

b. Using a 3/16" Nut driver, remove four M/F Hex Standoffs item 6 (Fig. 3.2).

c. Remove and replace the LCD.



d. Install the new LCD by reversing the above steps. Torque the fasteners to 2 in-lb. (*Note: The four M/F Hex Standoffs are the shortest standoff inside the pump)*

5 RE-INSTALL THE PCB following the instruction described in the section "**Install the PCB**", (Pg. 68).

6 INSTALL THE PUMP MECHANISM following the instructions described in the section "**Install Pump Mechanism**" (Pg. 65).

7 CLOSE PUMP CASE following the instructions described in the section "**Close the Pump**" (Pg. 81).

8 PERFORM FUNCTIONAL TEST following the procedure in Chapter 5 (Pg.40).

Replacement of LEMO Connector*

1 OPEN PUMP AND REMOVE THE PUMP MECHANISM following the instructions described in the section "**Opening Pump Case**" (Pg. 61).

2 REMOVE PCB following the instructions described in the section "**Replacement of Electronic PCB**", steps 2a through 2c.

3 REPLACE THE LEMO CONNECTOR AS FOLLOWS:

   a. Carefully remove the conformal coating material (RTV) on the PCB where the wires from the LEMO connector are soldered.

   b. Note the solder location of each of the color wire and carefully unsolder them off the PCB.

   c. Solder the wires of the new LEMO connector to the PCB by following the solder location from step b.

   d. Clean the soldering area with alcohol and apply RTV over the first ½" of LEMO connector wires and the PCB. Let the RTV cure overnight. The RTV will serve as a strain relief for these wires.

4 RE-INSTALL THE PCB following the instruction described in the section "**Install the PCB**", (Pg. 68).

5 INSTALL THE PUMP MECHANISM following the instructions described in the section "**Install Pump Mechanism**" (Pg. 65).

6 CLOSE PUMP CASE following the instructions described in the section "**Close the Pump**" (Pg. 81).

7 PERFORM FUNCTIONAL TEST following the procedure in Chapter 5 (Pg. 40).

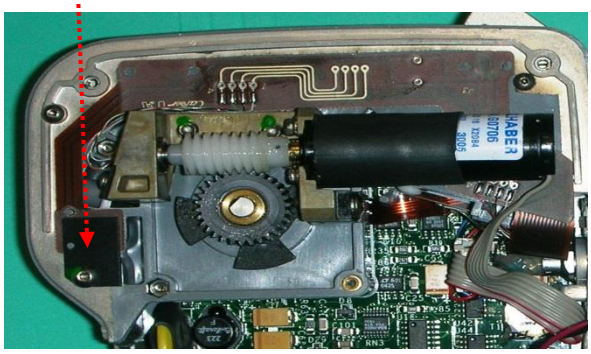
***The Lemo Connector can only be replaced if you have a current IPC certification for the 7711B/7721B Standards.**

Replacement of Tubing Guide Sensor Plunger

1 OPEN PUMP REAR CASE following the instructions described in the section "**Opening Pump Case**" (Pg. 61).

2 REPLACE THE TUBING GUIDE SENSOR PLUNGER AS FOLLOWS:

a. Using the 1/16" Hex driver, loosen the screw #4-40x1/4" BHCS item 1 (Fig. 2.9) and remove the Tubing Guide Sensor Bracket item 2 (Fig. 2.9) from the mechanism.



b. Carefully lift up the Flex Circuit and remove the Tubing Guide Sensor Spring item 3 (Fig. 2.9), and Tubing Guide Sensor Plunger item 4 (Fig. 2.9) from the mechanism.

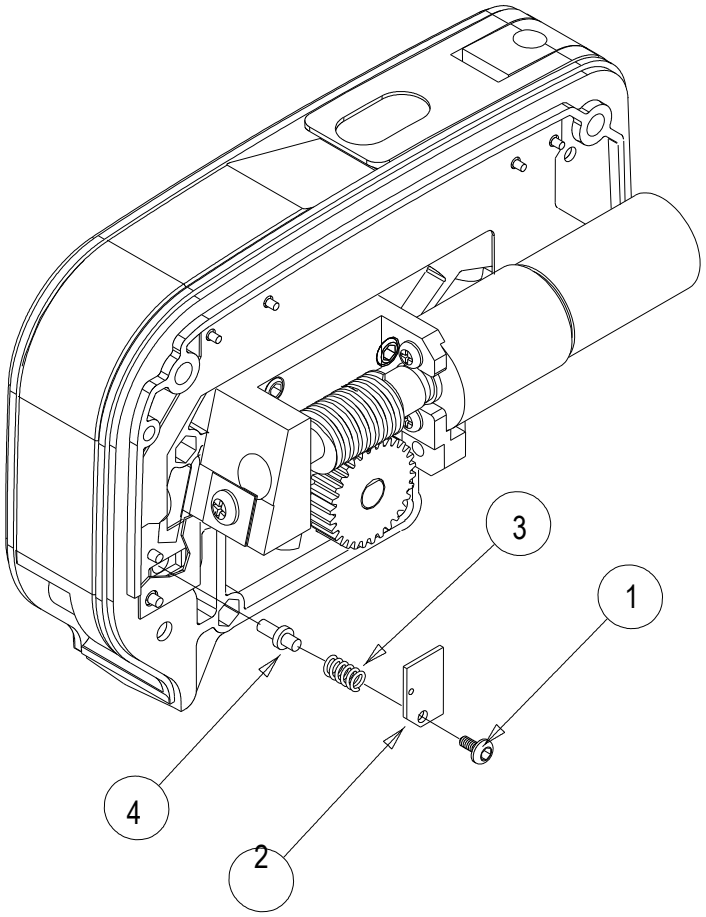
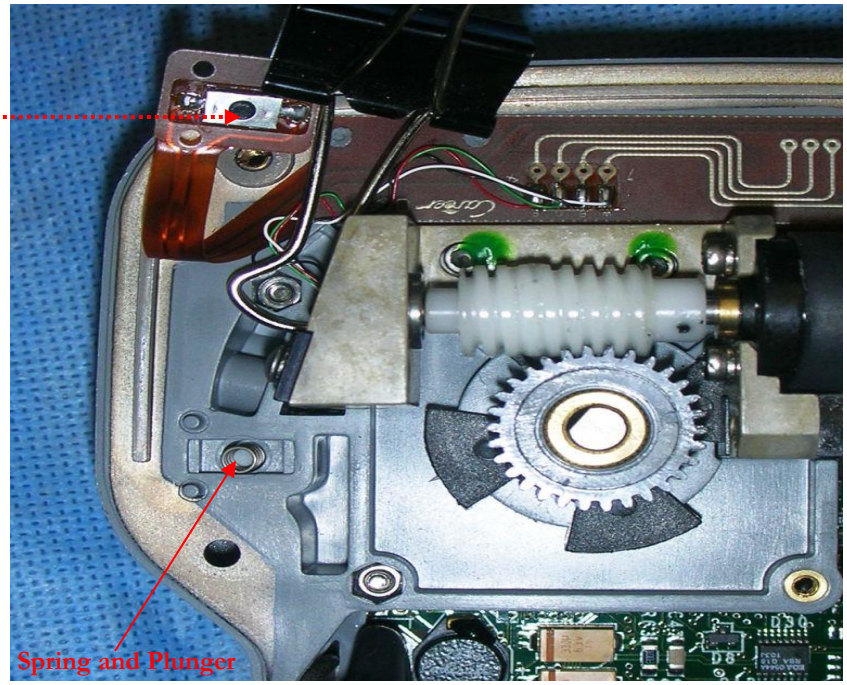


Figure 2.9 Tubing Guide Sensor Assembly

c. Note the orientation of the Tubing Guide Sensor Plunger.

d. If the Micro Switch on the flex circuit has a black actuator, replace the Tubing Guide Sensor Plunger with P/N: 340-0081. (approx. 0.275")



e. If the Micro Switch on the flex circuit has a white actuator, replace the Tubing Guide Sensor Plunger with P/N: 340-0082. (approx. 0.271")

f. Install the Tubing Guide Sensor Plunger and Tubing Guide Sensor Spring by reversing the orders in step b.

g. Secure the assembly with the Tubing Guide Sensor Bracket and one #4-40x1/4" BHCS item 1 (Fig. 2.9). Torque fastener to 4 in-lb.

h. Apply Torque Seal (C60-04010) over the old torque seal to the interface area of the #4-40x1/4" BHCS and the Tubing Guide Sensor Bracket. Let the Torque Seal to cure overnight.

3 CLOSE THE PUMP CASE following the instructions described in the section "**Close the Pump**" (Pg. 81).

4 PERFORM FUNCTIONAL TEST following the procedure in Chapter 5 (Pg. 40).

Replacement of Electronic Components

1 TO REPLACE COMPONENTS on the PCB refer to malfunction and corrective action table in chapter 1, to identify the component to be replaced. Refer to figures 2.6 and 2.7 for locating the component on the PCB.

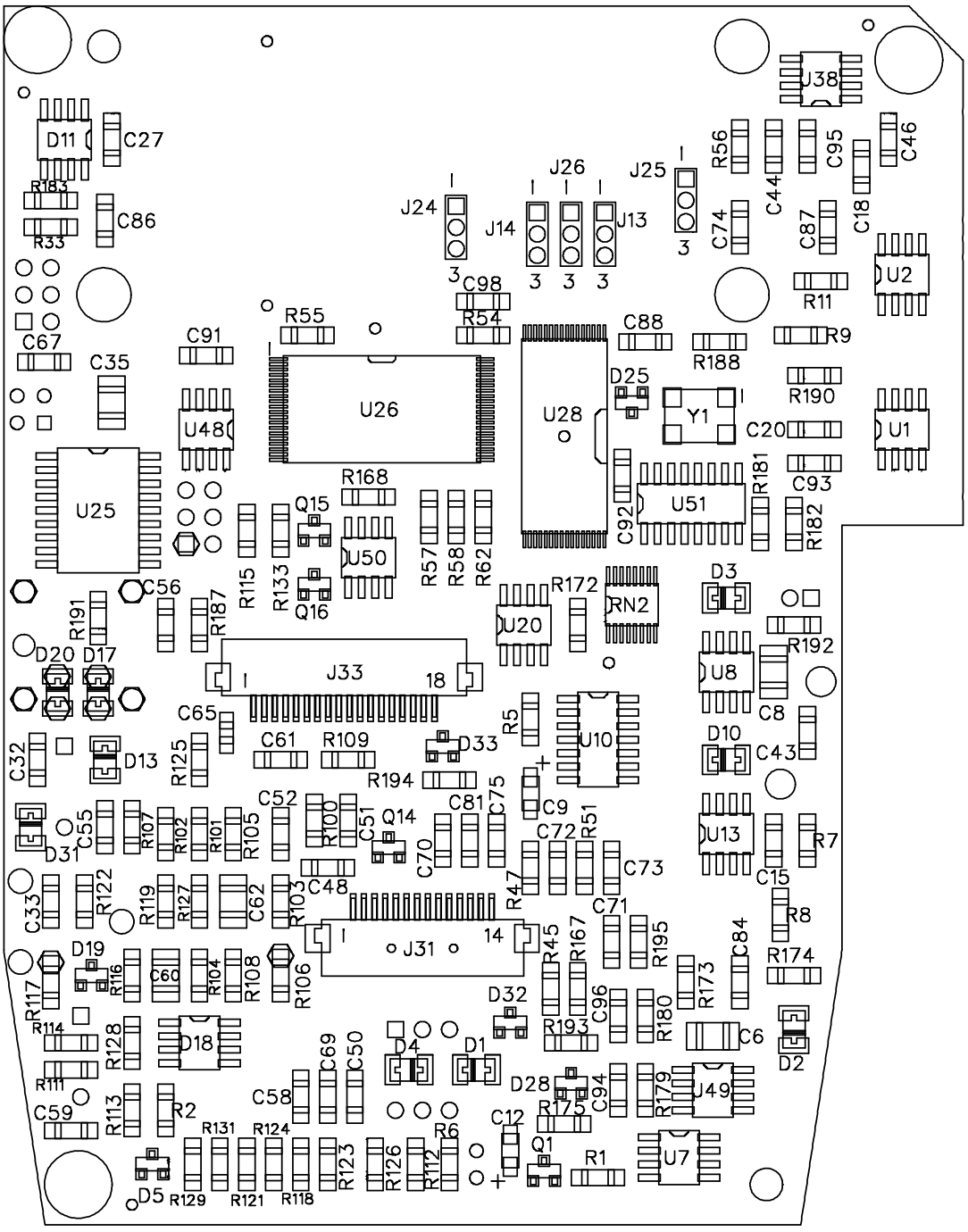


Figure 2.6 Front Side of Electronic PCB Assembly 4000

2 REPLACING COMPONENTS ON THE PCB will require the same level of tests as with replacing the PCB. (Perform PCB component replacements only if you have a current certification for IPC 7711B/7721B standards.)

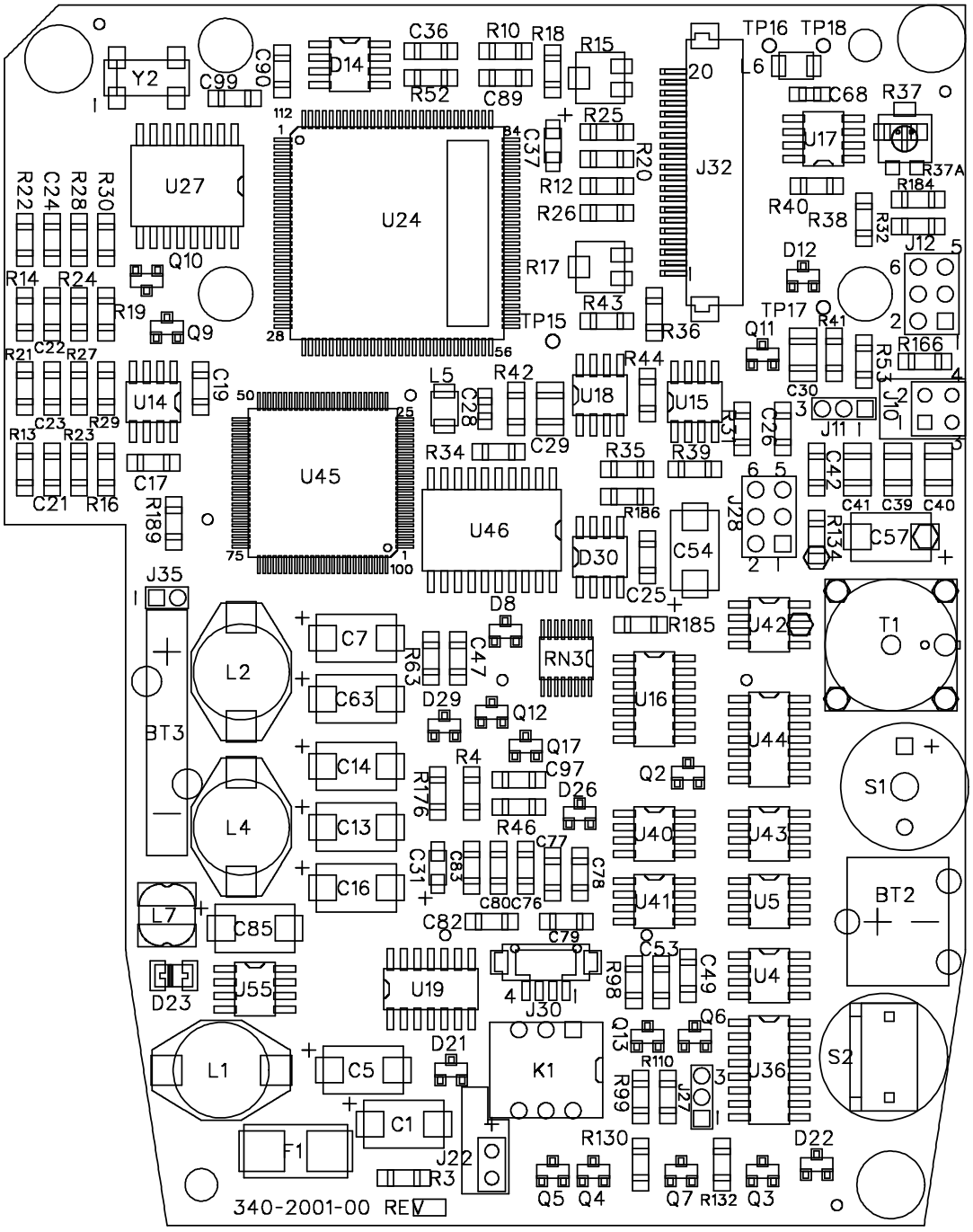


Figure 2.7 Back Side Of Electronic PCB Assembly 4000

3 Replacement of BT2 and BT3 only. No other component diagnostics or replacement on PCB is allowed. Refer to Fig. 3.5 and Fig. 3.6 for locating the component on the PCB. **(Perform PCB component replacement only if you have a current certification for IPC 7711B/7721B standards.)**

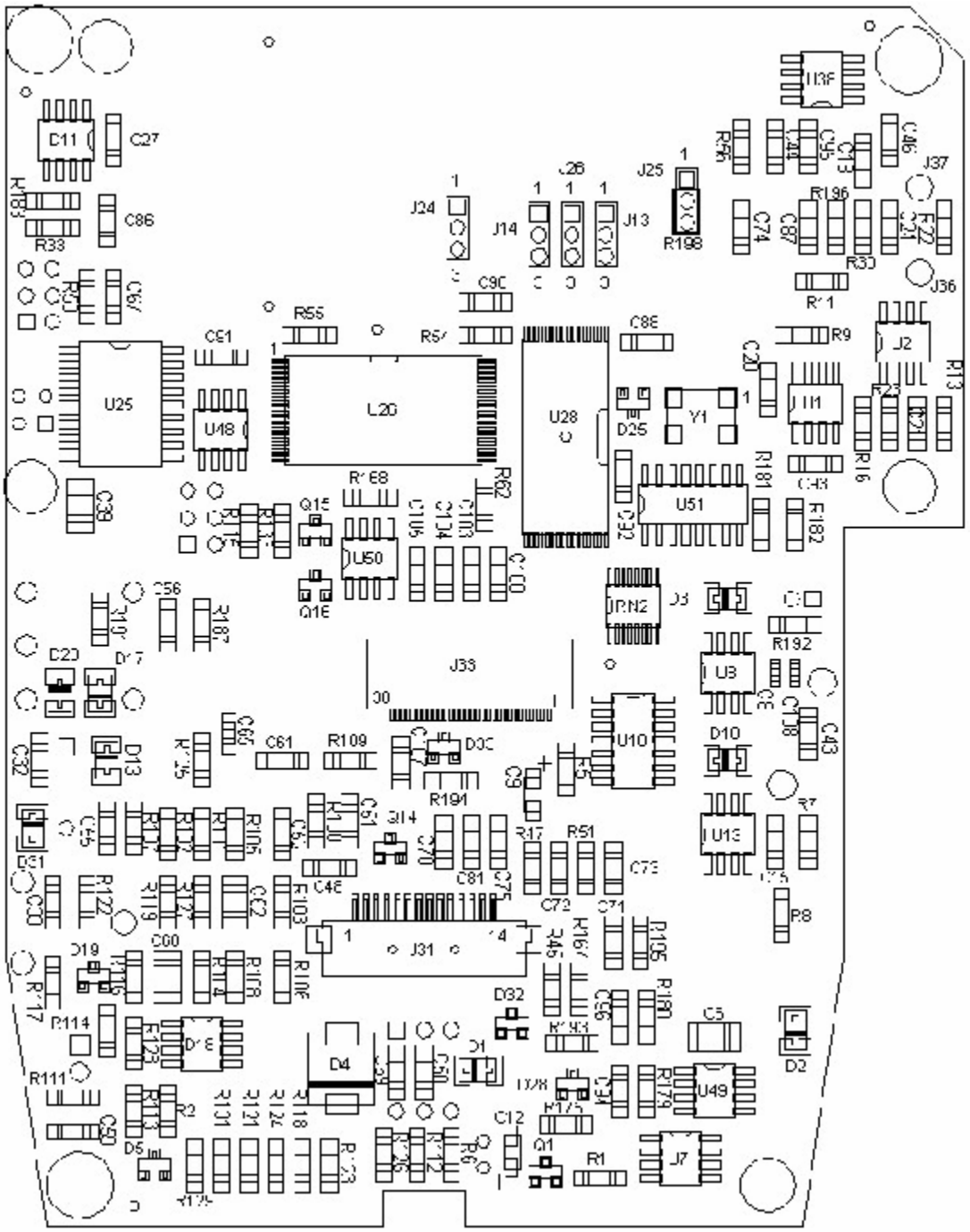


Figure 3.5 Front Side of Electronic PCB Assembly 6000

2 Replacing BT2 and BT3 on the PCB will require the same level of tests as with replacing the PCB. **(Perform PCB component replacement only if you have a current certification for IPC 7711B/7721B standards.)** Follow the steps as outlined in the section "**Replacement of Electronic PCB**". All work on the PCB must follow the IPC 7711B/7721B standards.

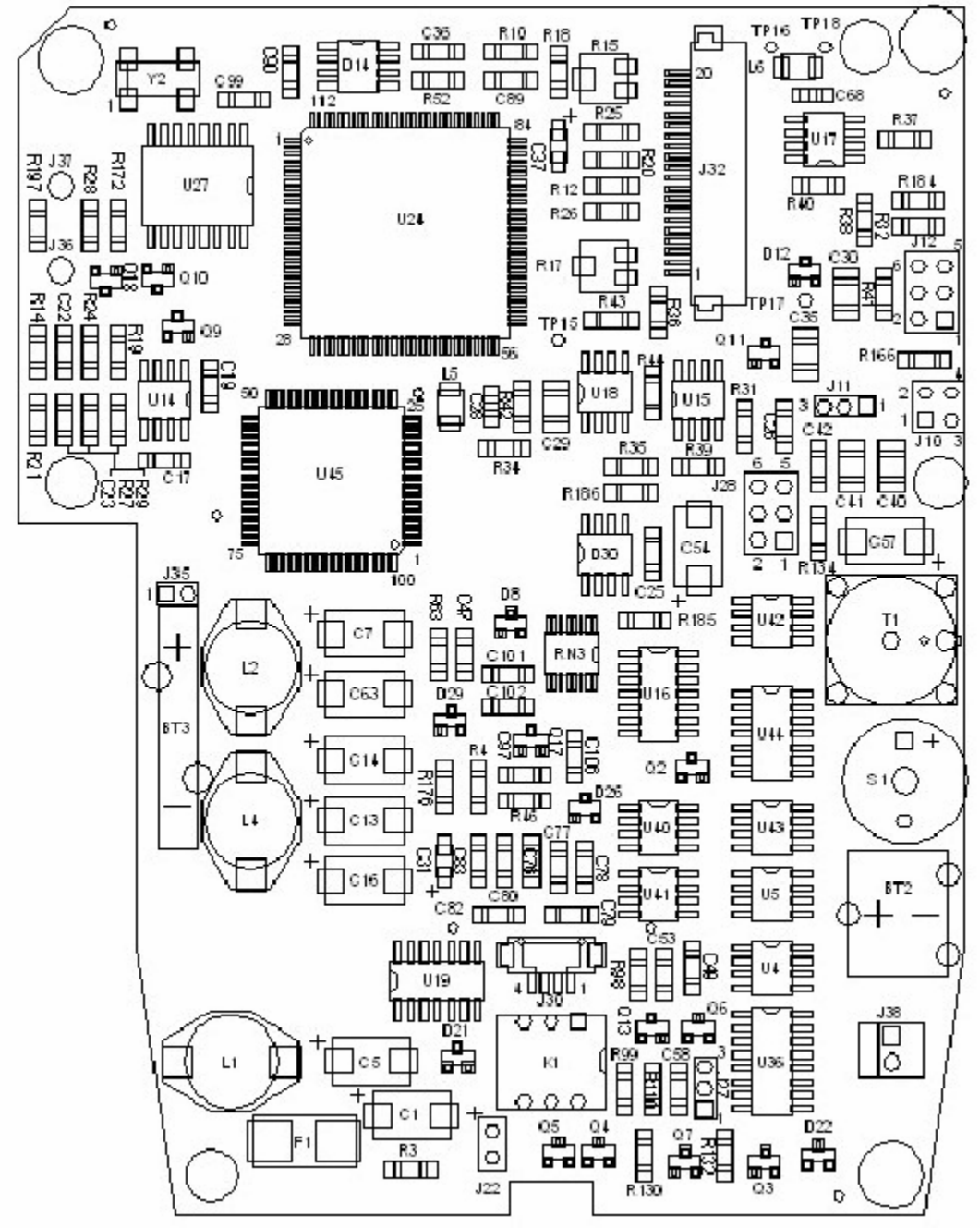


Figure 3.6 Back Side of Electronic PCB Assembly 6000

CLOSE THE PUMP CASE

a. To close the Pump Case, route the Motor Cable by folding it at its midpoint. There should be no twist in the cable. Align the folded cable along the right side of the case and slip it beside the battery cavity along the Bolus connector side of the case. *Note: Ensure that the Seal Gasket is properly installed in the Front Case Groove.*

b. Route the main Speaker Cable along the lower Bolus connector side of the Rear Case beside the battery cavity.

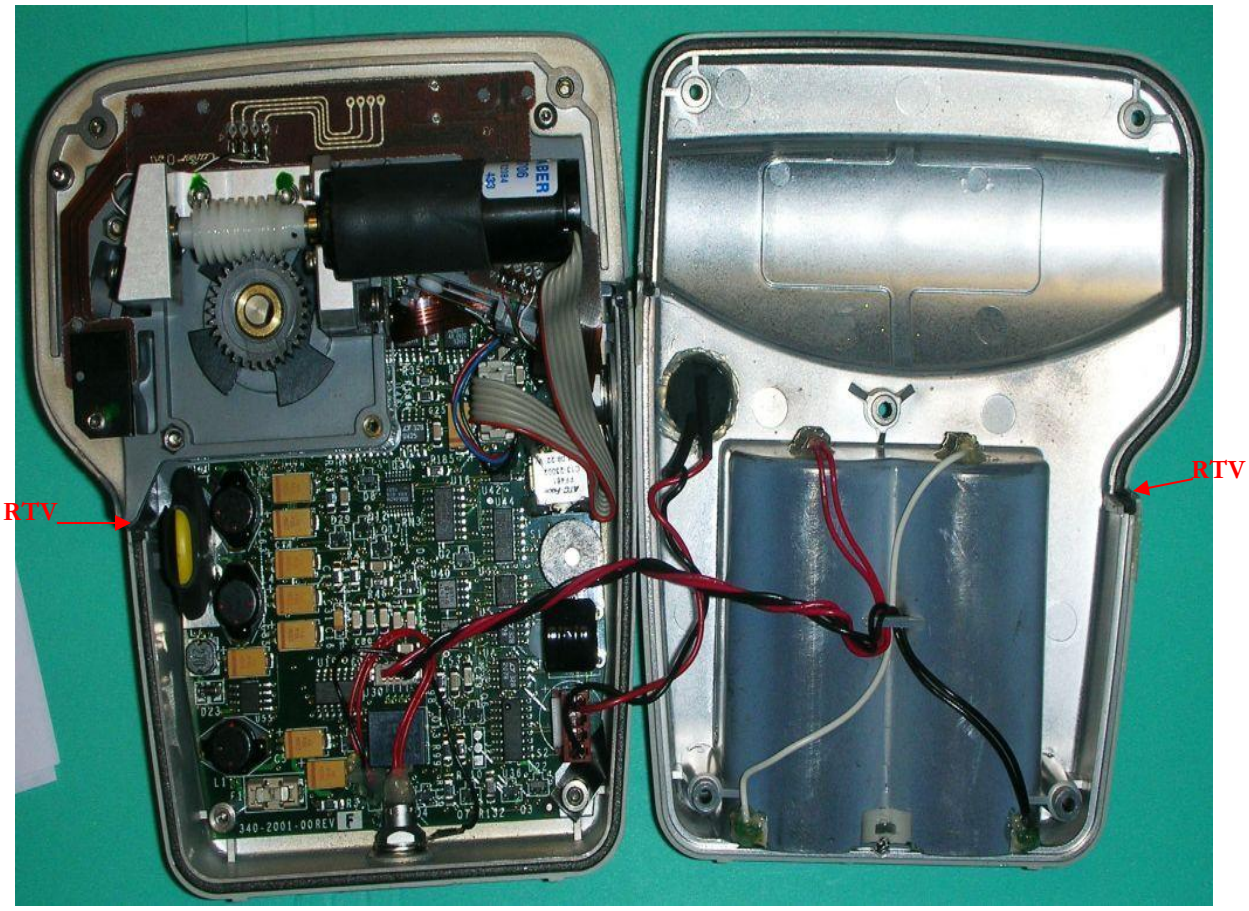
c. Loop the Battery Cable up towards and under the mechanism along the middle of the PC Board.

d. Clean the interior of the FRONT & REAR CASE with compress air and then apply a small bead of RTV at the two areas where the gasket of the FRONT and REAR CASE meet.

e. Close and secure the FRONT & REAR CASE with three #2-56x1/4" SHCS, and two #2-56x1/2" SHCS (lower side of the Rear Case). Torque fasteners to 3 lb-in.

f. PERFORM VOLUME ACCURACY CALIBRATION by following the procedure described in Chapter 5 (Pg. 64).

g. PERFORM FUNCTIONAL TEST following the procedure in Chapter 5 (Pg.40).



Pump Case Assembly

Chapter 8: Calibration

Volume Accuracy Calibration

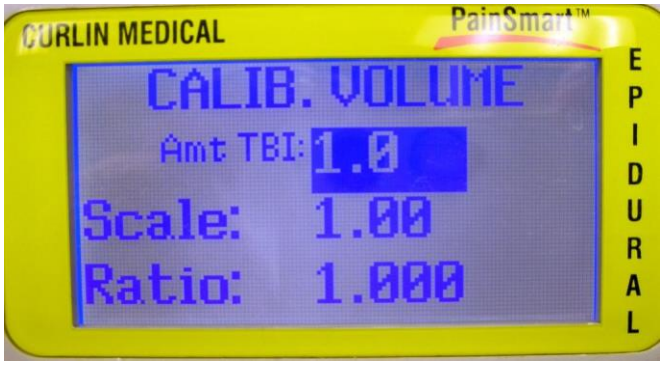
1 REQUIRED EQUIPMENT

The following equipments are required to calibrate the volumetric accuracy of the pump:

a. Scale – Minimum resolution 0.01 g. Minimum capacity 250 g.
b. Calibrated Test Set (Moog P/N: 340-4038).
c. 18 Gage Needle (Moog P/N 52281).
d. 2 Beakers. Minimum capacity 200 ml.
e. Water – Distilled water (specific gravity 0.998).
f. AC Adapter (Moog P/N: 340-2026 / 340-2022).
g. Non-Factory Recertification Software, NFR (Moog P/N: 350-7021/AS-45914).
h. Non-Factory Service Traveler (Moog P/N: 350-9041).
i. Data Interface Cable for PC (Moog P/N: 340-2011).
j. Personal Computer with Microsoft Windows: 2000 or XP.
k. Calculator
l. Head height is 12" (see diagram pg. 30)

2 VOLUME DELIVERY CALIBRATION

a. Obtain a **Calibrated** Test Set (340-4038) with a known **Set Offset Value**. *(Special order from Moog, each set can be used to calibrated 10 pumps)*
b. Connect the pump to the AC Adapter.
c. Install the administration set into the pump that requires calibration.
d. Set Calibration Volume ratio to 1.000:
   i Connects the PC Serial Port connector to Bolus/Data connector of the pump to be serviced. Turn on the pump and Press the "Door Sensor and Tubing Guide" button on the NFR Software (Moog P/N 350-7021/AS-45914.) Press "Down Arrow" once and then "No" on the pump when instructed by the PC.
   ii Scroll up to the CALIB VOLUME field and press YES.



iii Set the CALIB VOLUME menu as follows: You must enter 1 even if it is displayed.

AMT TBI: 1.0
SCALE: 1.0
RATIO: 1.000

iv Press "YES/ENTER" on the "ACCEPT?" field.

v Scroll to bottom of the Factory Biomed Screen and press "YES/ENTER" on the "DONE?" field.

e. Program Continuous Infusion at a bag volume of 100, TBI of 35 and a rate of 100 ml/hr:

f. Prime all the air out of the system.

g. Zero the Scale.

h. Start the Infusion by pressing the "RUN/PAUSE" key.

i. When infusion completes, obtain and record the Calculated Value on the Non-Factory Service Traveler using the following "Equation 1". Use 2 digits of precision.

Calculated Value = (Actual Amount Infused x 35.0) / Set Offset Value

Actual Amount Infused = The total weight in grams of the infusion as read off the Scale

Set Offset Value = The value printed on the Calibrated Test Set label

Equation 1

j. Set new Calibration Volume Ratio:

i Turn on the pump and Press the "Door Sensor and Tubing Guide" button on the NFR software (Moog P/N 350-7021/AS-45914.). Press "Down Arrow" once and then "No" on the pump when instructed by the PC.

ii Scroll to the CALIB VOLUME field and press YES.

iii Set the CALIB VOLUME menu as follows:

AMT TBI: 35.0
SCALE: (Enter the Calculated Value)
RATIO: (New ratio will be calculated)

iv Record the displayed RATIO on the Non-Factory Service Traveler.

v Press "YES/ENTER" on the "ACCEPT?" field.

k. Scroll to bottom of the Factory Biomed Screen and press "YES/ENTER" on the "DONE?" field.

3 Test Volume Delivery Accuracy without Down Stream Pressure.

a. Continue to use the same setup and calibration set in the pump.

b. RATE of 125 ml/hr test:

i Program pump to do a Continuous Therapy:

Pre Rx:

UNITS: ml
DELAY: OFF
Titrate: OFF
NEXT? YES

Prescription:

BAG VOL: 100 ml
VOL TBI: 10.0 ml
RATE: 125 ml/hr
TIME: 0:04 HH:MM
KVO Rate: 0.0 ml/hr
DONE? YES

ii Set the scale to zero.

iii Start the continuous therapy running by pressing "RUN/Pause" key.

iv When the 10 ml infusion is over, obtain and record the Calculated Value on the Non-Factory Service Traveler using "Equation 1". Passing measurement is: 9.80g ≤ scale measurement ≤ 10.20g.

Calculated Value = (Actual Amount Infused x 35.0) / Set Offset Value

Actual Amount Infused = The total weight in grams of the infusion as read off the Scale

Set Offset Value = The value printed on the Calibrated Test Set label

v Record all results on the Non-Factory Service Traveler.

Pressure Sensors Baseline Calibration

1 REQUIRED EQUIPMENT

The following equipments are required to calibrate the pressure sensor baseline of the pump:

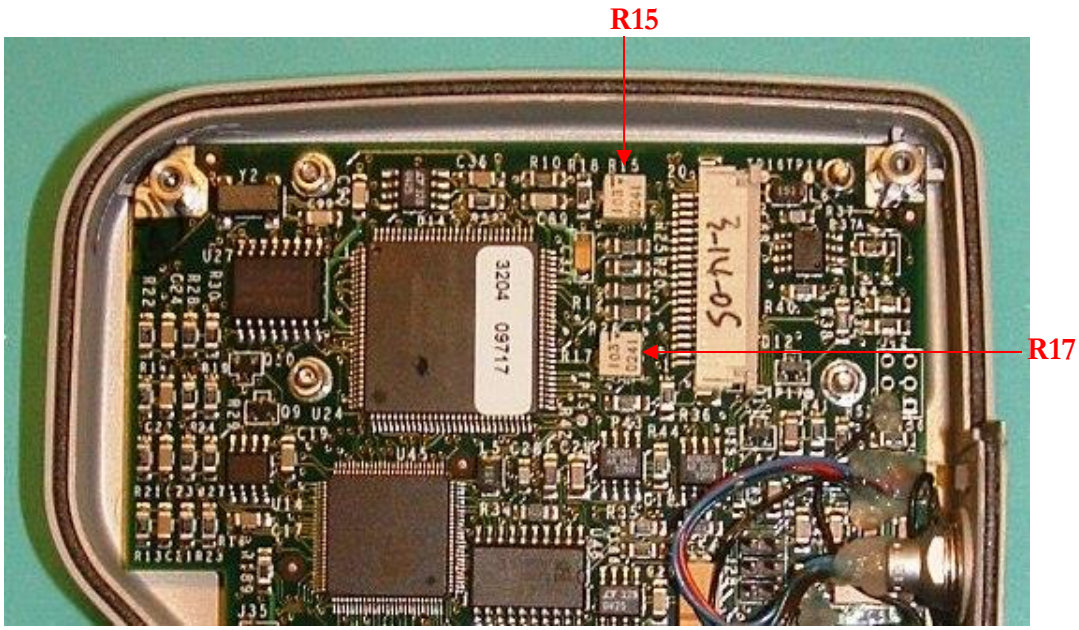
a. A new Moog Test Admin Set (Moog P/N: 340-4123-02).
b. AC Adaptor (Moog P/N: 340-2004 / 340-2022).
c. Non-Factory Recertification Software, NFR (Moog P/N: 350-7021/AS-45914).
d. Non-Factory Service Traveler (Moog P/N: 350-9041).
e. Data Interface Cable for PC (Moog P/N: 340-2011).
f. Personal Computer with Microsoft Windows: 2000 or XP.
g. Digital Timer
h. Flat Head Driver (Moog P/N: C56-50038)

2 PRESSURE SENSOR BASELINE CALIBRATION

Calibration of Pressure Sensors (Strain Beam) Baseline is performed with the Pump Case open as follows:

a. OPEN THE PUMP CASE by following the instructions described in Chapter 4, the section "**Opening Pump Case**" (Pg. 61). Do Not Disconnect the Flex Circuit Cable at J32.
b. Connect the pump to the AC Adapter and turn pump on.
c. Connect the PC Serial Port connector to Bolus/Data connector of the pump to be serviced. Turn on the pump and Press the "Door Sensor and Tubing Guide" button on the NFR software (Moog P/N 350-7021/AS-45914.) Press "Down Arrow" once and then "No" on the pump when instructed by the PC.
d. Scroll up to DISP STRAINS then press the "YES/ENTER" key.

e. Install a new Moog Test Administration Set (340-4123-02) into mechanism and close latch. *(Special order from Moog, each set can be used to calibrate 3 pumps)*
f. Start a timer.
g. Observe the voltage readout for the Output Strain Beam (OutStr:) on the LCD display, and allow the reading to settle for 3 minutes (according to timer).



h. At the 3 minute point, adjust the Trim Pot R17 (Potentiometer) on the PCB so that the output strain beam (OutStr:) reads 1.700 volts (±0.050 volts). Use the flat-head driver for this.

i. Allow the timer to continue and observe the voltage readout for the Input Strain Beam (InStrn:).

j. At the 4 minute point, adjust the trim pot R15 so that the input strain beam (InStrn:) reads 2.100 volts (±0.050 volts). Use the flat head driver for this.

k. Record both strain beam voltage readings on the Non-Factory Service Traveler.

l. Open Pump Door and remove the Administration Set, then check the unloaded Strain Beam voltages readout on the LCD Display. Voltages for both strain beams must be less than or equal to 0.050 volts. Record the unloaded strain beam voltages.

m. Press the "YES/ENTER" key to exit the DISP STRAINS screen.

n. Record all results on the Non-Factory Service Traveler.

Pressure Sensors Calibration

3 REQUIRED EQUIPMENT

The following equipments are required to calibrate the pressure sensor of the pump:

a. Digital Pressure Gage (-30 to 60 PSI range).

b. Moog Test Admin Sets (Moog P/N: 340-4123-02).

c. 2 Beakers. Minimum capacity 200 ml.

d. Water – Distilled water (specific gravity 0.998).

e. 3-way valve suitable for connecting to Moog administration sets.

f. Male-Male Adapter (Moog P/N: 340-4039).

g. AC Adaptor (Moog P/N: 340-2004 / 340-2022).

h. Non-Factory Recertification Software, NFR (Moog P/N: 350-7021/AS-45914).

i. Non-Factory Service Traveler (Moog P/N: 350-9041).

j. Data Interface Cable for PC (Moog P/N: 340-2011).

k. Personal Computer with Microsoft Windows: 2000 or XP.

4 PRESSURE SENSORS (STRAIN BEAMS) CALIBRATION.

a. The strain beam pots should have already been calibrated. See Chapter 5, the section "**Pressure Sensor Baseline Calibration**" (Pg. 85).

b. Install a new Moog Test Administration Set (340-4123-02) into mechanism. *(Special order from Moog, each set can be used to calibrated 3 pumps)*

c. Calibrate Output strain beam for 8 and 18 PSI Thresholds:

i Before calibration, the pump should be turned on for 5 minutes.

ii Connect the Digital Pressure Gage, Syringe and a 3-way valve to the downstream side of the Moog Test Admin Set such that the syringe can pressurize the downstream while the pressure gage reads the pressure.

iii If you are performing this after doing the Baseline Calibration, the pump would be at the CAL OUT STRAIN field. Press the "YES/ENTER" key.

iv If you are not at the Biomed Setup menu, connect the pump to the NFR software and press the "Door Sensor and Tubing Guide" buton. When it settles down at the Maintenance Due Date, arrow down once and select NO in the ACCEPT? Field. Then scroll up until you see CAL OUT STRAIN. Press the YES/ENTER key.

v Observe the un-pressurized zero reading and allow the reading to settle for approximately 1 minute. The reading should be approximately 1.700 volts (± 0.3). Press the "YES/ENTER" key to accept the zero pressure reading.

vi Pressurize the output side to 8 PSI using the syringe and the reading from the pressure gage. Press the "YES/ENTER" key when the pressure gage reads 8.0 PSI (± 0.5). Do not release the pressure.

vii Increase the pressure using the syringe to 18 PSI. When the pressure gage reads 18.0 PSI (± 0.5) press the "YES/ENTER" key. Release pressure on the syringe.

d. Calibrate Input strain beam for –6 PSI threshold.

i Remove the syringe, pressure gage and 3-way valve from the output side of the administration set and connect them to the input side with a Male-Male Adapter.

ii Select the CAL IN STRAIN field by pressing the "YES/ENTER" key.

iii Observe the un-pressurized zero reading which must be approximately 2.100 volts (± 0.30). Let it settle for one minute then press the "YES/ENTER" key to accept the zero pressure reading.

iv De-pressurize the input side to -6 PSI (-12.2 inHg) using the syringe and the reading from the pressure gage. Press the "YES/ENTER" key when the pressure gage reads -6.0 PSI (± 0.5) (-12.2 +/- 1 inHg).

v Scroll down the menu and Press "YES/ENTER" key on the "DONE?" field.

5 TEST OF PRESSURE SENSORS CALIBRATION.

a. The pressure sensor should have already been calibrated. See Chapter 8, the section "**Pressure Sensor Calibration**" (Pg. 86).

b. Install a primed Moog Test Administration Set (340-4123-02) into mechanism.

c. Test Output Strain Beam for 8 and 18 PSI Thresholds:

i Connect the Digital Pressure Gage and a 3-way valve to the downstream side of the Moog Test Admin Set such that the pressure gage can read the down occlusion pressure.

ii Program pump to do a New Continuous Therapy:

Pre Rx:

UNITS: ml

DELAY: OFF
Titrate: OFF
NEXT? YES

Prescription:

BAG VOL: 100 ml
VOL TBI: 50.0 ml
RATE: 9.9 ml/hr
TIME: 5:03 HH:MM
KVO Rate: 0.0 ml/hr
DONE? YES

iii Start the continuous therapy running by pressing "RUN/Pause" key.

iv While the pump is running, occlude the output by closing the 3-way valve for the return to the beaker.

v Observe pressure buildup on the pressure gage. Pump will go into ALARM DOWN OCCLUSION when pressure reaches 8 PSI. Valid pressure range for low occlusion is 6.0 ≤ occlusion pressure ≤ 10.0 PSI.

vi Release the pressure by opening the 3-way valve and observe pump automatically restarts infusion when pressure is released.

vii Change the down occlusion threshold to High (18 PSI) using the "Option" menu.

viii While the pump is running, occlude the output by closing the 3-way valve for the return to the beaker.

ix Observe pressure buildup on the pressure gage. Pump will go into ALARM DOWN OCCLUSION when pressure reaches 18 PSI. Valid pressure range for low occlusion is 16.0 ≤ down occlusion pressure ≤ 20.0 PSI.

x Release the pressure by opening the 3-way valve and observe pump automatically restarts infusion when pressure is released.

d. Test Input Strain Beam for -6 PSI Thresholds:

i Connect the Digital Pressure Gage and a 3-way valve to the upstream side of the Moog Test Admin Set such that the pressure gage can read the up occlusion pressure.

ii Resume the previous continuous therapy.

iii While the pump is running, occlude the input by closing the 3-way valve towards the reservoir.

iv Observe the inlet pressure falls and pump will go into ALARM UP OCCLUSION when pressure reaches -6 (-12.2 inHg). Valid pressure range is -8 ≤ up occlusion pressure ≤ -4 PSI (-16.3 ≤ up occlusion pressure ≤ -8.1 inHg).

v Release the pressure occlusion and observe pump will NOT restart infusion automatically. Press the Run/Pause key and resume the infusion.

e. Record all results on the Non-Factory Service Traveler.

Chapter 9:

Notify MOOG of Successful Self-Recertification

After a successful recertification a copy of the completed traveler and the pump history printout must be sent to Moog. This allows Moog to update its Device History List for the pump just recertified. Please mail a copy of the completed traveler and the pump history printout to:

Moog Medical Devices Group
Attn: Moog Self Re-certification Program
4314 Zevex Park Lane
Salt Lake City, Utah 84123
Or
FAX (801) 264-1051

You may also choose to scan the results and email it to:

medcustomerservice@moog.com

If a pump fails the recertification, please call Moog Customer Support at (800) 970-2337 to obtain a Call ID prior to returning the pump.